EXHIBIT C

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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. PELVIC :MDL NO. 2327

REPAIR SYSTEM, PRODUCTS

LIABILITY LITIGATION :VOLUME II

:

THIS DOCUMENT RELATES TO ALL CASES AND VARIOUS OTHER CROSS-NOTICED ACTIONS

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

January 8, 2014

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Transcript of the continued deposition of THOMAS A. BARBOLT, Ph.D., called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Michelle L. Gray, a Certified Court Reporter, Registered Professional Reporter, and Notary Public, at the offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at 9:07 a.m.

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Golkow Technologies, Inc. - 1.877.370.DEPS

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1 APPEARANCES:		1					
2 3 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC		2		INDEX			
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7 THOMAS, COMBS & SPANN, PLLC 8 BY: DAVID B. THOMAS, ESQUIRE		7	By M	Mr. Thomas	557		
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Appearing on behalf of the Defendants; Ethicon, 12 Inc.; Ethicon Women's Health and Urology, a Division of Ethicon, Inc.; Gynecare; and Johnson & Johnson		13 14	NO. T-2248	DESCRIPTION Binder Titled	PAGE 307		
13 14		15 16		IFU-1 Animal Studies Volume I			
15 16		17 18		Tabs 1-32			
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21 22		22 23		Tabs 33-44			
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1 APPEARANCES VIA TELEPHONE:		1 2		EXHIBITS (Cont	·!d)		
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC BY: BOBBY J. (BRAD) BRADFORD, ESQUIRE BY: D. RENÉE BAGGETT, ESQUIRE		3			. u.)		
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5 (850) 202-1010 rbaggett@awkolaw.com		5	NO. T-2250	DESCRIPTION Critical Reviews	PA 350	GE	
6 Representing the Plaintiffs 7		7	1-2230	In Biocompatibility	5 330		
FREEARK, HARVEY & MENDILLO, P.C. 8 BY: RANSOM P. WULLER, ESQUIRE		8		Volume I, Issue 3			
115 West Washington Street 9 Belleville, Illinois 62222		9		1985 ETH.MESH.105753	201 /52		
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Representing Heartland Women's Healthcare, 11 Ltd., and Dr. Elisabeth G. Beyer-Nolen		12	T-2251	Long-Term Con		378	
BONNE, BRIDGES, MUELLER, O'KEEFE & NICHOLS BY: SUSAN FAYE L. FRANCISCO, ESOUIRE		13		Study of Nonabsorb	able		
13 BY: SUSAN FAYE L. FRANCISCO, ESQUIRE 3699 Wilshire Boulevard, 10th Floor 14 Los Angeles, California 90010		14		Sutures (Postlethwait)			
(213) 738-5842 15 sfrancisco@bonnebridges.com		16		ETH.MESH.105757	759-64		
Representing Gerald Thorpe, M.D.; Keller vs. 16 Siddighi, et al., San Bernardino County Superior		17	T. 22.72	0/10/00	201		
Court, case No. CIVDS1307951		18 19	T-2252	8/10/90 Ten Year In Vivo S	391		
18 VIDEOTAPE TECHNICIAN:		20		Study Scanning Ele			
19 Lee Bittman		21		Microscopy Five Yo	ear Report		
		22		ETH.MESH.111336	5474-87		
20 21 TRIAL TECHNICIAN:				E111VIES11.111 330	, , , , , , , , , , , , , , , , , , , ,		
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1		1	within the IFU, that you were designated as a
2	DEPOSITION SUPPORT INDEX	2	witness to discuss.
3 4		3	Do you recall that IFU statement?
	tion to Witness Not to Answer	4	A. Yes.
6 PAGE	E LINE	5	Q. Go ahead and take out Exhibit
None		6	Number 2246, which is the IFU that we marked
7 8 Reque	est for Production of Documents	7	yesterday.
	E LINE	8	THE VIDEOGRAPHER: Off the record.
423		9	(Brief pause.)
10		10	THE VIDEOGRAPHER: Back on the video
Stipul 11	ations	11	record, 9:10.
	E LINE	12	BY MR. THORNBURGH:
12 None		13 14	Q. Doctor, do you have Exhibit
	ions Marked	15	Number 2246?
14 PAGE None	ELINE	16	A. Yes. Q. And do you recall that you had a
15		17	discussion yesterday regarding this claim in the
16		18	IFU?
17		19	The first claim is: Animal studies
18 19		20	show the implantation of Prolene mesh elicits a
20		21	minimal inflammatory reaction in tissues, which is
21		22	transient, and can and is followed by the
22		23	deposition of a thin fibrous layer of tissue, which
23 24		24	can grow through the interstices of the mesh, thus
25		25	incorporating the mesh into the adjacent tissue.
	Page 304		Page 306
1		1	Do you recall that?
2	THE VIDEOGRAPHER: We're now on the	2	A. Yes.
3 reco	ord.	3	Q. From yesterday, right?
4	Today is January 8, Year 2014. It's	4	A. Yes.
5 9:07	a.m.	5	Q. And you had identified in
6	This begins Volume 2, Tape Number 1	6	Exhibit 2241 a list of I believe it was I'm
	ne videotape deposition of Dr. Thomas A.	7	sorry. Maybe we didn't mark it yesterday the IFU
8 Barb		8	binder that you have in front of you.
9	Please proceed.	9	Let's go ahead and mark both of those
10		10	binders as exhibits.
11 12 haar	THOMAS A. BARBOLT, Ph.D., having	11	We'll mark the first one as Exhibit
12 been 13 follo	n previously sworn, was examined and testified as	12 13	Number 2248.
14	JWS.	14	MR. THOMAS: Do you mind if I identify the volumes?
15	CONTINUED EXAMINATION	15	MR. THORNBURGH: Go ahead.
16		16	(Whereupon, a discussion was held off
	MR. THORNBURGH:	17	the record.)
	Q. Good morning, Doctor.	18	MR. THOMAS: For the record, Volume 1
	A. Good morning.	19	of the documents that have been provided to the
	Q. How are you doing this morning?	20	plaintiffs in response to the notice of deposition
	A. Very good.	21	for the language in the information for use just
	Q. Another cold day in New Jersey?	22	identified by counsel.
23	A. It will change.	23	Exhibit 2248 is Volume 1, which
	Q. Doctor, we talked a little bit about	24	contains Tabs 1 through 32 of those documents.
25 the l	IFU yesterday, and a statement that you were	25	(Whereupon, a discussion was held off

4 (Pages 303 to 306)

1 majority of those are suture studies, right? 2 A. There are some suture studies in that 3 list. 4 Q. Well, I said vast majority of those 5 are suture studies, right? 6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real 8 quick. 9 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 21 Diological evaluation in rabbits, which is from 2 1973, which is the study that we ended talking at 3 from yesterday, correct? 4 A. Yes. 5 Q. And in that study, it showed that 4 there was chronic inflammation seen in all rats in all rabbits in that study at the end period of 4 there, but there was the record of chronic 1 inflammation in some rabbits at the 28-day time 2 point. 20 And, by the way, that rabbit study 1 that you did that formed the basis of the claim in 1 the IFU was a short-term study, correct? 20 MR. THOMAS: Object to the form of 1 the question. 21 BY MR. THORNBURGH: 22 Q. Tab's considered in the laboratory		Page 307		Page 309
2 MR. THOMAS: Exhibit 2249 is Volume 2 topic just discussed by counsel. And these are topic just discussed by counsel. And these are documents upon which Dr. Barbolt relies in support of that designation. (Document marked for identification as Exhibit 7-2248) (Document marked for identification as Exhibit 7-2249) (Document marked for identification as Exhibit 7-249) (Document marked for identification as Exhibit 7-249) (Document marked for identification as Exhibit 7-249) (Document marked for identification as Exhibit 7-24	1	the record)	1	O Okay And that study is related to
define studies which are responsive to the 30(b)(6) topic just discussed by counsel. And these are topic just a preparable labels. That's a study, but that's a suture study, correct? A. Yes. Q. The next one is a epoxy-tipped nylon and Prolene biological evaluation. That's also a suture document, isn't it? A. Yes. Q. The next one is a epoxy-tipped nylon and Prolene biological evaluation. That's also a suture document, isn't it? A. Yes. Q. The next one is a epoxy-tipped nylon and Prolene biological evaluation. That's also a suture document, isn't it? A. Yes. Q. The next one is a epoxy-tipped nylon and Prolene biological evaluation. That's also a suture document, isn't it? A. Yes. MR. THOMAS: Object to the form of the question. The war yes. Q. Add, that's just a repeat of what's up here, it appears, but from 1973, right, also suture? MR. THOMAS: Object to the form of the question. The war yes. Q. Add ifferent version, but updated 22 version from 1973 related to sutures, correct? A. Yes, that's correct. A. Yes, that's correct. A. Yes, that's correct. A. Yes, that's up here, it appears, but from 1973, right, also suture? The WITNESS: Yeah. It's a different version. By MR. THORNBURGH: 1973, which is the study, that we ended talking at from yesterday, correct? A. I would have to look at the endering of that study, at day 28, correct? A. I would have to		·		- •
topic just discussed by counsel. And these are Tabs 33 through 34 produced by Ethicon and as documents upon which Dr. Barbolt relies in support of that designation. (Document marked for identification as Exhibit T-2248.) (Document marked for identification as Exhibit T-2249.) BY MR. THORNBURGH: Q. Okay. Now. Doctor, do you agree with me that this claim in the IFU says that animal studies show the implantation of Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. And it discusses in the first saminal studies relate to Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. Okay. And in the — in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast That a Sab. A Yes. A. There are some suture studies in that list. A				<u> </u>
5 Tabs 33 through 34 produced by Ethicon and as documents upon which Dr. Barbolt relies in support of that designation. (Document marked for identification as Exhibit T-2248.) (Document marked for identification (Document marked for identification as Exhibit T-2249.) (Document marked for identification (Document marked for identification as Exhibit T-2249.) (Document marked for identification (Document in the intervity and Prolene ibiological evaluation. A Yes. Q O Okay, Now, Doctor, do you agree with that it is a suture study, correct? A Yes. Q And it discusses in the first sentence, that the animal studies relate to Prolene mesh. Correct? A Yes. Q O Okay, And in the — in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the vast part of exhibits numbered 2248 and 2249, the				
6 documents upon which Dr. Barbolt relies in support 7 of that designation. 8 (Document marked for identification 9 as Exhibit T-2248.) 9 (Document marked for identification 11 as Exhibit T-2249.) 12 BY MR. THORNBURGH: 13 Q. Okay. Now, Doctor, do you agree with 14 me that this claim in the IFU says that animal 15 studies show the implantation of Prolene mesh 16 elicits a minimal inflammatory reaction in tissues 17 which is transient. Right? 18 A. Yes. 19 Q. And it discusses in the first 20 sentence, first part of that sentence, that the 21 animal studies relate to Prolene mesh. Correct? 22 A. Yes. 23 Q. Okay. And in the — in the documents 24 that you submitted or the list that you submitted as 25 part of exhibits numbered 2248 and 2249, the vast 26 majority of those are suture studies, right? 2 A. There are some suture studies in that 3 list. 4 Q. Well, I said vast majority of those 3 are suture studies, right? 4 Q. Okay. Well, let's look at it real 4 quick. 5 Your Tab Number 1 in Exhibit 2248 is 5 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 18 THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, correct? 14 A. Yes. 15 biological evaluation in rabbits, which is from 1973, which is the study that we ended talking ab from yesterday, correct? 16 A. Yes. 17 biological evaluation in rabbits, which is from 1973, which is the study at the end period of that study, at day 28, correct? 18 A. Yes. 19 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 5, it says excerpt from NDA 17 A. Yes. 18 Page 308 18 Correct? 19 A. Yes. 10 A. Yes. 11 biological evaluation in rabbits, which is from 1973, which is the study at the end period of that study, at day 28, correct? 19 A.				
7 of that designation. (Document marked for identification as Exhibit T-2248.) 10 (Document marked for identification as Exhibit T-2248.) 11 as Exhibit T-2248.) 12 BY MR. THORNBURGH: 13 Q. Okay. Now, Doctor, do you agree with me that this claim in the IFU says that animal studies show the implantation of Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? 18 A. Yes. 19 Q. And it discusses in the first sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? 21 animal studies relate to Prolene mesh. Correct? 22 A. Yes. 23 Q. Okay. And in the in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast 1 majority of those are suture studies, right? 2 A. There are some suture studies in that list. 3 list. 4 Q. Well, I said vast majority of those are suture studies, right? 5 are suture studies, right? 6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real quick. 9 Your Tab Number 1 in Exhibit 2248 is a suture study, correct? 10 A. Yes. 11 biological evaluation. 12 he question. 13 bist. 4 Q. Well, I said vast majority of those are suture studies in that list at a suture study, correct? 24 hat a sextence first part of that sentence, that the animal studies relate to Prolene mesh. Correct? 25 Page 308 26 Dial MR. THORNBURGH: 27 A. Yes. 28 A. Yes. 29 A. THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, correct? 29 A. Yes, that's correct. 20 A. different version, but updated version from 1973 related to sutures, correct? 21 biological evaluation in rabbits, which is from 1973, which is the study that we ended talking at from yesterday, correct? 30 A. Yes. 31 bist. 4 Q. Well, I said vast majority of those are suture study, correct? 4 A. I didn't make that assessment. 5 Q. Tab 2 is a suture study, correct? 4 A. Yes. 5 Q. Tab 2 is a suture study, correct? 4 A. Yes. 6 A. Yes. 9 Your				
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9 and Prolene biological evaluation. 10 as Exhibit T-2248.) 11 as Exhibit T-2249.) 11 as Exhibit T-2249.) 11 as Exhibit T-2249.) 12 BY MR. THORNBURGH: 13 Q. Okay. Now, Doctor, do you agree with methat this claim in the IFU says that animal studies show the implantation of Prolene mesh clicia minimal inflammatory reaction in tissues thich is transient. Right? 18 A. Yes. 19 Q. And it discusses in the first entence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? 20 A. Yes. 21 Q. Okay. And in the in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast 25 part of exhibits numbered 2248 and 2249, the vast 26 part of exhibits numbered 2248 and 2249, the vast 27 A. There are some suture studies in that list. 28 A. There are some suture studies in that list. 39 A. There are some suture studies in that list. 40 Q. Well, I said vast majority of those are suture studies, right? 41 A. Yes. 42 Q. And in that study, it showed that there was chronic inflammation seen in all rats-rate and a suture study, correct? 41 A. Yes. 42 Q. Tab 2 is a suture study, correct? 43 A. Yes. 44 Q. Tab 3 is a suture study, correct? 45 A. Yes. 65 Q. Tab 2 is a suture study, correct? 66 Q. Tab 3 is a suture study, correct? 77 A. Yes. 78 Q. Tab 4 is a suture study, correct? 89 Your Tab Number 1 in Exhibit 2248 is a suture study, correct? 90 Your Tab Number 1 in Exhibit 2248 is a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 5 is a systure study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA and that study it the open deal that point. 18 the question. 19 THE WITNESS: Yeah. It's a different excerpt from NDA the question. 19 The question. 19 The question. 19 The wits unders to the form of the question. 19 The wits unders to the form of the question. 19 The wits unders to the form of the question. 19 The wits unders to the form of the ques				
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12 BY MR. THORNBURGH: 13 Q. Okay. Now, Doctor, do you agree with 14 me that this claim in the IFU says that animal 15 studies show the implantation of Prolene mesh 16 elicits a minimal inflammatory reaction in tissues 17 which is transient. Right? 18 A. Yes. 29 Q. And it discusses in the first 21 animal studies relate to Prolene mesh. Correct? 21 animal studies relate to Prolene mesh. Correct? 22 A. Yes. 23 Q. Okay. And in the — in the documents 24 that you submitted or the list that you submitted as 25 part of exhibits numbered 2248 and 2249, the vast 26 part of exhibits numbered 2248 and 2249, the vast 27 Q. Well, I said vast majority of those 28 are suture studies, right? 29 A. There are some suture studies in that 30 list. 4 Q. Well, I said vast majority of those 30 a suture studies, right? 4 Q. Okay. Well, let's look at it real 4 Q. Okay. Well, let's look at it real 5 quick. 5 You Tab Number 1 in Exhibit 2248 is 5 a suture study, correct? 6 A. Yes. 7 Q. Tab 2 is a suture study, correct? 8 Your Tab Number 1 in Exhibit 2248 is 8 a suture study, correct? 9 Your Tab Number 1 in Exhibit 2248 is 10 A. Yes. 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 12 A. Yes. 13 Q. And, there tat bin your notebook, 14 except from NDA 1634, that's just a repeat of 15 what's up here, it appears, but from 1973, right, 16 elicts a minimal inflammatory reaction in fissues 18 the question. 19 THE WITNESS: Yeah. It's a different version, but updated 20 version. 21 BY MR. THORNBURGH: 22 Q. A different version, but updated 23 version from 1973 related to sutures, correct? 24 A. Yes, that's correct. 25 Q. Tab 1 said vast majority of those 26 are suture studies, right? 27 A. Yes. 28 A. Yes. 29 Your Tab Number 1 in Exhibit 2248 is 29 A. I would have to look at the specifics 20 Tab 2 is a suture study, correct? 21 A. Yes. 22 A. Yes. 23 Q. And, by the way, that rabit study 24 A. Yes. 25 D. And, by the way, that rabit study 26 there was chronic inflammation in some rabbits at the 28-day time 27 in all rabbits in that study, at day 28,		· ·		· · · · · · · · · · · · · · · · · · ·
Q. Okay. Now, Doctor, do you agree with me that this claim in the IFU says that animal studies show the implantation of Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. And it discusses in the first sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? A. Yes. Q. Okay. And in the in the documents that you submitted as part of exhibits numbered 2248 and 2249, the vast Page 308 page 3		· ·		
me that this claim in the IFU says that animal studies show the implantation of Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. And it discusses in the first sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? A. Yes. Q. Okay. And in the in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast spart of exhibits numbered 2248 and 2249, the vast spart of exhibits numbered 248 and 259 are suture studies, right? A. There are some suture studies in that list. Q. Well, I said vast majority of those are suture studies in that list. Q. Okay. Well, let's look at it real quick. Q. Okay. Well, let's look at it real quick. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5 it says excerpt from NDA 18 to question. 18 what's up here, it appears, but from 1973, right, also suture; also suture; also suture. MR. THOMAS: Object to the form of the question. 18 the question. 19 THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, correct? 20 A. Yes, that's correct. Q. Tab 4 is a suture studies in that sudy submitted as part of exhibits numbered 2248 and 2249, the vast should a suture study that we ended talking at from yesterday, correct? 4 A. Yes. Q. And in that study, it showed that there was chronic inflammation in some rabbits at the 28-day time point. 10 the question. 11 in all rabbits in that study at the end period of that study, at day 28, correct? 12 point. 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5 it says excerpt from NDA 18 WR. THORNBURGH: 29 C. And, by the way, that rabbit				
studies show the implantation of Prolene mesh elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. And it discusses in the first sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? A. Yes. Q. Okay. And in the in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast Page 308 A. Yes. Q. Well, I said vast majority of those are suture studies, right? A. I didn't make that assessment. Q. Okay. Well, let's look at it real quick. Your Tab Number 1 in Exhibit 2248 is a suture study, correct? A. Yes. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 3 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5, it says excerpt from NDA 18 the question. THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, of the question. THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, orrect? A. Yes. Q. A Mitferent version, but updated version from 1973 related to sutures, correct? A. Yes, that's correct. Q. Tab 4 is a witure studies in that study at updated version from 1973 related to sutures, correct? A. Yes. Q. Tab 4 is a suture studies in that study at updated version from 1973 related to sutures, correct? A. Yes. Q. Tab 4 is a suture studies in that study at updated version from 1973 related to sutures, correct? A. Yes. Q. And in that study, it showed that there was chromic inflammation in some rabbits in that study at the end period of the there was chromic inflammation in some rabbits at the 28-day time point. A. Yes. Q. Tab 5 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5, it says excerpt from NDA 15 in HEWITNESS: Dis a spoutare study version. THE WITNESS: Vaal. It's a different version, but updat				
elicits a minimal inflammatory reaction in tissues which is transient. Right? A. Yes. Q. And it discusses in the first sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? A. Yes. Q. Okay. And in the in the documents that you submitted as part of exhibits numbered 2248 and 2249, the vast The wild part of exhibits numbered 2248 and 2249, the vast The majority of those are suture studies, right? A. There are some suture studies in that list. Q. Well, I said vast majority of those are suture studies, right? A. I didn't make that assessment. Q. Okay. Well, let's look at it real quick. Your Tab Number 1 in Exhibit 2248 is a suture study, correct? A. Yes. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 3 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5, it says excerpt from NDA 16374, package insert, labeling approved 1969. That's also suture? MR. THOMAS: Object to the form of the question. THE WITNESS: Yeah. It's a different version, but updated version from 1973 related to sutures, correct? A. Yes, that's correct. Page Version. THE WITNESS: Yeah. It's a different version. The question. THE WITNESS: Yeah. It's a different version. The question. The question. The question. The question. The question. The part of that sentence, that the question in the question. The question. The question. The question in the question in the question in rabbits, which is from the prolene mest page and p				
which is transient. Right? A. Yes. Q. And it discusses in the first enimal studies relate to Prolene mesh. Correct? A. Yes. Q. Okay. And in the — in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast Page 308 majority of those are suture studies, right? A. There are some suture studies in that list. Q. Well, I said vast majority of those are suture studies, right? A. I didn't make that assessment. Q. Okay. Well, let's look at it real quick. Your Tab Number 1 in Exhibit 2248 is a suture study, correct? A. Yes. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 3 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5, it says excerpt from NDA 18 7 MR. THOMAS: Object to the form of the question. THE WITNESS: Yeah. It's a different version. BY MR. THORNBURGH: Q. A different version, but updated version from 1973 related to sutures, correct? A. Yes, that's correct. Q. The next document is the Prolene mesh from yesterday, correct? A. Yes. Q. And in that study that we ended talking at from yesterday, correct? A. Yes. Q. And in that study, it showed that there was chronic inflammation seen in all rats — in all rabbits in that study at the end period of the stat study, at day 28, correct? A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time point. A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time point. A. Yes. A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time point. A. Yes. A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time point. A. Yes. A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the				
18 the question. 19 Q. And it discusses in the first sentence, first part of that sentence, that the sentence, first part of that sentence, that the animal studies relate to Prolene mesh. Correct? 21 A. Yes. 22 Q. Okay. And in the in the documents that you submitted or the list that you submitted as part of exhibits numbered 2248 and 2249, the vast 25 part of exhibits numbered 2248 and 2249, the vast 26 part of exhibits numbered 2248 and 2249, the vast 27 Page 308 28 Page 308 29 Page 308 20 Well, I said vast majority of those are suture studies, right? 29 A. There are some suture studies in that is list. 30 list. 40 Well, I said vast majority of those are suture studies, right? 51 A. I didn't make that assessment. 71 Q. Okay. Well, let's look at it real quick. 9 Your Tab Number 1 in Exhibit 2248 is a suture study, correct? 10 A. Yes. 11 and I rabbits in that study at the end period of that study, at day 28, correct? 12 A. Yes. 13 A. Yes. 14 Q. Tab 2 is a suture study, correct? 15 A. Yes. 16 Q. Tab 3 is a suture study, correct? 17 A. Yes. 18 Q. Tab 4 is a suture study, correct? 19 I 6374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 21 Br HE WITNESS: Yeah. It's a different version. 22 version. 23 PAGE 4 A. Yes, that's correct. 24 A. Yes, that's correct. 25 Q. A different version, but updated version from 1973 related to sutures, correct? 4 A. Yes, that's correct. 26 Q. Tab 4 is a vature studies, right? 27 D. A A Yes, that's correct. 28 Page 308 Page 308 Page 308 Page 4 A. Yes, that's correct. 4 A. Yes, that's correct. 4 A. Yes, that's correct. 5 Q. And in that study, it showed that there was chronic inflammation seen in all rats -in all rabbits in that study at the end period of that study at day 28, correct? 4 A. Yes. 5 Q. Tab 2 is a suture study, correct? 4 A. Yes. 5 Q. And in that study at the end period of their study at the end pe				
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1 majority of those are suture studies, right? 2 A. There are some suture studies in that 3 list. 4 Q. Well, I said vast majority of those 5 are suture studies, right? 6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real 8 quick. 9 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 21 Diological evaluation in rabbits, which is from 2 1973, which is the study that we ended talking at 3 from yesterday, correct? 4 A. Yes. 5 Q. And in that study, it showed that 4 there was chronic inflammation seen in all rats in all rabbits in that study at the end period of 4 there, but there was the record of chronic 1 inflammation in some rabbits at the 28-day time 2 point. 20 And, by the way, that rabbit study 1 that you did that formed the basis of the claim in 1 the IFU was a short-term study, correct? 20 MR. THOMAS: Object to the form of 1 the question. 21 BY MR. THORNBURGH: 22 Q. Tab's considered in the laboratory	23	•	23	•
A. There are some suture studies in that list. Q. Well, I said vast majority of those are suture studies, right? A. I didn't make that assessment. Q. Okay. Well, let's look at it real quick. Your Tab Number 1 in Exhibit 2248 is a suture study, correct? A. Yes. A. Yes. A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time Q. Tab 2 is a suture study, correct? A. Yes. A. Yes. Q. Tab 3 is a suture study, correct? A. Yes. A. Yes. A. Yes. A. Twould have to look at the specifics inflammation in some rabbits at the 28-day time point. Q. And, by the way, that rabbit study that you did that formed the basis of the claim in the IFU was a short-term study, correct? MR. THOMAS: Object to the form of MR. THOMAS: Object to the form of The question. The WITNESS: It's a 28-day study. That's also a suture NDA, correct? Q. That's considered in the laboratory		Page 308		Page 310
3 list. 4 Q. Well, I said vast majority of those 5 are suture studies, right? 6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real 8 quick. 9 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 2 A. I from yesterday, correct? 4 A. Yes. 5 Q. And in that study, it showed that 6 there was chronic inflammation seen in all rats 7 in all rabbits in that study at the end period of 8 that study, at day 28, correct? 9 A. I would have to look at the specifics 10 there, but there was the record of chronic 11 inflammation in some rabbits at the 28-day time 12 point. 13 Q. And, by the way, that rabbit study 14 that you did that formed the basis of the claim in 15 the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of 17 A. Yes. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 That's considered in the laboratory	1	majority of those are suture studies, right?	1	biological evaluation in rabbits, which is from
4 Q. Well, I said vast majority of those 5 are suture studies, right? 6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real 8 quick. 9 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 2 Q. And in that study, it showed that 4 A. Yes. 5 Q. And in that study, it showed that 6 there was chronic inflammation seen in all rats 7 in all rabbits in that study at the end period of 8 that study, at day 28, correct? 9 A. I would have to look at the specifics 10 there, but there was the record of chronic 11 inflammation in some rabbits at the 28-day time 12 point. 13 Q. And, by the way, that rabbit study 14 that you did that formed the basis of the claim in 15 MR. THOMAS: Object to the form of 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 That's considered in the laboratory	2	A. There are some suture studies in that	2	1973, which is the study that we ended talking about
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6 A. I didn't make that assessment. 7 Q. Okay. Well, let's look at it real 8 quick. 9 Your Tab Number 1 in Exhibit 2248 is 10 a suture study, correct? 11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 16 there was chronic inflammation seen in all rats 7 in all rabbits in that study at the end period of 8 that study, at day 28, correct? 9 A. I would have to look at the specifics 10 there, but there was the record of chronic 11 inflammation in some rabbits at the 28-day time 12 point. 13 Q. And, by the way, that rabbit study 14 that you did that formed the basis of the claim in 15 the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 That's considered in the laboratory	4	Q. Well, I said vast majority of those	4	A. Yes.
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Your Tab Number 1 in Exhibit 2248 is a suture study, correct? A. Yes. Q. Tab 2 is a suture study, correct? A. Yes. Q. Tab 3 is a suture study, correct? A. Yes. Q. Tab 4 is a suture study, correct? A. Yes. Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. To a suture study, correct? A. I would have to look at the specifics there, but there was the record of chronic inflammation in some rabbits at the 28-day time point. 12 point. 13 Q. And, by the way, that rabbit study that you did that formed the basis of the claim in the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of the question. 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory	8	quick.	8	that study, at day 28, correct?
11 A. Yes. 12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 11 inflammation in some rabbits at the 28-day time point. 12 point. 13 Q. And, by the way, that rabbit study that you did that formed the basis of the claim in the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of the question. 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 That's considered in the laboratory	9		9	A. I would have to look at the specifics
12 Q. Tab 2 is a suture study, correct? 13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 12 point. 13 Q. And, by the way, that rabbit study 14 that you did that formed the basis of the claim in 15 the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory	10	a suture study, correct?	10	there, but there was the record of chronic
13 A. Yes. 14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 12 Q. And, by the way, that rabbit study 14 that you did that formed the basis of the claim in 15 the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory	11	A. Yes.	11	inflammation in some rabbits at the 28-day time
14 Q. Tab 3 is a suture study, correct? 15 A. Yes. 16 Q. Tab 4 is a suture study, correct? 17 A. Yes. 18 Q. Tab 5, it says excerpt from NDA 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 14 that you did that formed the basis of the claim in 15 the IFU was a short-term study, correct? 16 MR. THOMAS: Object to the form of 17 the question. 18 THE WITNESS: It's a 28-day study. 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory	12	Q. Tab 2 is a suture study, correct?	12	point.
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16Q. Tab 4 is a suture study, correct?16MR. THOMAS: Object to the form of17A. Yes.17the question.18Q. Tab 5, it says excerpt from NDA18THE WITNESS: It's a 28-day study.1916374, package insert, labeling approved 1969.19BY MR. THORNBURGH:20That's also a suture NDA, correct?20Q. That's considered in the laboratory	14	Q. Tab 3 is a suture study, correct?	14	that you did that formed the basis of the claim in
17A. Yes.17 the question.18Q. Tab 5, it says excerpt from NDA18THE WITNESS: It's a 28-day study.1916374, package insert, labeling approved 1969.19BY MR. THORNBURGH:20That's also a suture NDA, correct?20Q. That's considered in the laboratory	15	A. Yes.	15	the IFU was a short-term study, correct?
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 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory 	17	A. Yes.	17	the question.
 19 16374, package insert, labeling approved 1969. 20 That's also a suture NDA, correct? 19 BY MR. THORNBURGH: 20 Q. That's considered in the laboratory 	18	Q. Tab 5, it says excerpt from NDA	18	THE WITNESS: It's a 28-day study.
	19	16374, package insert, labeling approved 1969.	19	
	20	That's also a suture NDA, correct?	20	Q. That's considered in the laboratory
A. Yes. 21 science field to be a short-term study, tissue	21	A. Yes.	21	science field to be a short-term study, tissue
Q. The Postlethwait study that you have 22 reaction study, correct?	22	Q. The Postlethwait study that you have	22	reaction study, correct?
23 listed here isn't a study that you conducted, right? 23 MR. THOMAS: Objection.	23		23	ž.
A. This is a study from the open 24 THE WITNESS: Yes.	24		24	
25 literature. 25 BY MR. THORNBURGH:	25	literature.	25	BY MR. THORNBURGH:

5 (Pages 307 to 310)

	Page 311		Page 313
1	Q. The next study that you have listed	1	A. Yes.
2	in that binder is a Prolene polypropylene suture	2	Q. And as the ladies and gentlemen can
3	tissue response. That's another suture study,	3	see, the document I am holding up, the remaining
4	correct?	4	studies appear to be vast the vast majority of
5	A. Yes.	5	these studies are suture studies, right?
6	Q. The following study is a suture	6	MR. THOMAS: Object to the form of
7	study, correct?	7	the question.
8	A. Yes.	8	BY MR. THORNBURGH:
9	Q. Then there's another publication from	9	Q. Well, let's go through the exercise.
10	Postlethwait, which is also related to sutures,	10	Tab 16, Ethilon and Prolene ocular
11	correct?	11	tissue response. That's suture, right?
12	A. Well, I see Tab 14 is not the	12	A. Yeah.
13	Postlethwait. That is the next one in the list.	13	Q. The next document listed here is
14	Q. Well, Tab 14 is suture. Tab 15 is	14	another suture study, right?
15	suture, right?	15	A. Yes.
16	A. Yes.	16	Q. The following study is another suture
17	Q. Tab 16, Salthouse, that's a former	17	study, correct?
18	employee of Ethicon, isn't it?	18	A. Yes.
19 20	A. What was that? Tab 15?	19	Q. The following study, size 5-0 and
21	Q. Yep. A. Tab 15?	20 21	zero Prolene cobalt and ethylene oxide sterilized, effects of sterilization on tissue reaction.
22	A. Tab 15?Q. The tab after Postlethwait.	22	That's is that that was not
23	A. Tab 14.	23	looking at mesh, was it?
24	Q. You said it was 15 a moment ago.	24	A. That's a suture study.
25	Let's go ahead and mark that as 14.	25	Q. Right. And we're looking at the
	Page 312		Page 314
1	Tab 15 is Salthouse, right?	1	effects of EO, which is a sterility method, correct?
2	A. 14 is Salthouse.	2	A. Yes. It is a sterilization method.
3	Q. Okay. Let's make sure we're on the	3	Q. The next study that you have listed
4	same page here.	4	here is another suture study that looked at Procol
5	Tab 14. Salthouse is a former	5	versus Lubrol, which are antioxidants, additives
6	employee of Ethicon, right?	6	contained within the resin, correct?
7	A. Yes, that's correct.	7	A. Yes.
8	Q. And that's also a suture study,	8	Q. Again, it's related to sutures,
9	correct?	9	right?
10	A. Yes.	10	A. Yes.
11	Q. Tab 15 is another suture study?	11	Q. Prolene the next study is another
12	A. Yes.	12	suture study, followed by another suture study.
13	Q. Now, we can go through all these. I	13	Now we are at the FDA
14	don't want to waste anybody's time here, but you'd	14	reclassification of Prolene polypropylene
15	agree with me that the vast majority the	15	non-absorbable sutures.
16	overwhelming majority of these studies that you	16	That's related to sutures, right?
17	listed are suture studies, correct?	17	A. That's correct.
18	MR. THOMAS: Objection to form.	18	Q. The following study is a suture
19	THE WITNESS: I wouldn't make that	19	study, right?
20	statement unless I've gone through the exercise that	20	A. Yes.
21	you're doing. If you've done that, then I have no	21	Q. Prolene polypropylene suture. That's
		22	another suture study, right?
22	reason to doubt to doubt your conclusion.		
23	BY MR. THORNBURGH:	23	A. Yes.

6 (Pages 311 to 314)

Page 315 Page 317 1 A. Yes. 1 MR. THOMAS: Object to the form of 2 Now we're at the Prolene suture dyed Q. the question. 3 size stability study, Number 749. That's clearly a THE WITNESS: To look at the tissue 4 suture study, right? 4 reaction, integration, and response. 5 Yes. 5 BY MR. THORNBURGH: A. 6 6 Q. Followed by the 91-day ophthalmic Well, it was looking at -- the Q. 7 7 tissue reaction study in rabbits. specific endpoint in that study was looking at --8 That's a suture study, right? 8 for necrosis to determine if the Prolene in the TVT 9 9 A. Yes. was cytotoxic. 10 10 MR. THOMAS: Object. Q. Followed by a one-month dural tissue reaction study of dyed NGP. That's a suture study, 11 11 BY MR. THORNBURGH: 12 12 Right? right? Q. 13 13 A. Yes. MR. THOMAS: Objection to form. 14 14 Q. 182, intramuscular tissue reaction THE WITNESS: That's one of the 15 study in rats is a suture study, right? 15 endpoints of that study. 16 16 BY MR. THORNBURGH: 17 17 Q. Followed by six-month dural tissue Do you have that study with you? Q. 18 18 reaction absorption efficacy study of ETHISORB, A. Of course. which isn't even Prolene, is it? 19 19 Q. All right. Why don't you pull it out 20 That is a Dormier substitute for 20 and read what the purpose of that study was. 21 ETHISORB. This is the material that is part of 21 It should be in Tab 2 of your IFU. 22 22 TVT-S. I'll go to Tab 32 of my list of A. 2.3 23 It's not -- my question is very studies. 24 specific. Okay? It's a yes or no question. 24 Q. I meant to say Volume 2. 25 ETHISORB is not Prolene, is it? 25 I am looking on ETH.MESH.05315244, A. Page 316 Page 318 1 A. That's correct. the protocol. The purpose of the protocol. The 2 purpose of the study. The purpose of the study is Q. Then you have a 28-day intramuscular 3 tissue reaction study in rats with polypropylene to assess the tissue reaction of polypropylene mesh mesh from the TVT device. from the TVT (Ulmsten) device when implanted in rat 5 That is a study we looked at gluteal muscle for up to 28 days and to compare this reaction to that elicited by current production б yesterday that showed a moderate inflammatory б 7 response that was chronic, right? 7 Prolene polypropylene mesh. 8 MR. THOMAS: Objection to form of the 8 And you recall that that study was 9 9 conducted after the TVT device tested severely question. BY MR. THORNBURGH: 10 10 cytotoxic by one of your laboratories in Ohio, I think it was described as a mild to 11 right? 11 12 moderate inflammatory response, which was chronic, 12 MR. THOMAS: Object to the form of 13 13 the question. 14 MR. THOMAS: Object to the form of 14 THE WITNESS: To clarify, this study 15 was conducted after an in vitro cytotoxicity test 15 the question. THE WITNESS: I think you're thinking that showed -- in fact, there were two studies. One 16 showed a moderate in vitro cytotoxicity, and the 17 of the autoclave study that we discussed 17 other showed severe in vitro cytotoxicity. yesterday --18 18 BY MR. THORNBURGH: 19 BY MR. THORNBURGH: 19 20 I'm sorry. I thought that's what we 20 So the reason that you had decided to 21 21 were looking at here. conduct the study is to look at the in vivo So 28-day intramuscular tissue 22 cytotoxicity of the TVT device, correct? 22 23 reaction study that we discussed briefly yesterday, 23 A. Well, I just read the purpose of this 24 that was a study to look at the cytotoxic effect of experiment. 24 25 polypropylene, right? 25 Doctor, I don't -- Doctor, I mean --

7 (Pages 315 to 318)

Page 319 Page 321 1 MR. THOMAS: Let him answer the language was already in the IFU? 2 2 question, please, Dan. Yes. By 2000 that language was 3 3 MR. THORNBURGH: Well, he's not already in the IFU. And the purpose of that study was to 4 answering the question. 4 Q. 5 5 look at -- to see if the -- if Triclosan increased MR. THOMAS: Yes, he is. 6 6 MR. THORNBURGH: He knows the answer. the inflammatory response in tissue, right? 7 7 He's not being straightforward with the jury. Yes. 8 The reason that -- the reason why you 8 Q. The ISO intracutaneous reactivity 9 9 have -test in rabbits of Vypro mesh, Vypro Prolene 10 composite, September 25, 2000 -- 2000, that was a --MR. THOMAS: Stop just a minute. 11 Stop just a minute. Just a minute. that was a study that was -- well, do you know what 12 12 You're not going to characterize the the pore size of that Vypro Prolene composite was? 13 13 witness's testimony for the jury or anybody. You MR. THOMAS: Object to the form of 14 14 can ask him questions. the question. 15 MR. THORNBURGH: You can move to 15 THE WITNESS: I could determine that 16 16 strike. by looking at the document, but I think it would be 17 considered a large pore mesh. MR. THOMAS: If you --18 18 BY MR. THORNBURGH: BY MR. THORNBURGH: 19 Doctor -- Doctor, you know. You are 19 Q. Larger pores than are contained 20 the -- you were the investigator at Ethicon who 20 within the Prolene TVT, correct? 21 ordered that this study be conducted, right? 21 A. 22 22 A. Yes. Q. The next study is an exploratory 23 23 91-day tissue reaction study -- let me make sure I And you did it for the purpose of showing that the TVT device is not cytotoxic in got it right -- tissue reaction study in vivo. That was the reason why you did it, right? polypropylene-based surgical mesh in rats dated Page 320 Page 322 1 The purpose of this study is as 2001, right? 2 stated in the protocol, which is the overall 2 A. Yes. direction of the study. And that purpose was to 3 Q. After that language was already assess the tissue reaction of polypropylene mesh contained in the IFU, right? from TVT when implanted in rat gluteal muscle for up 5 A. б 6 to 28 days. Q. And, also, not a GLP study, was it? 7 7 Q. Were you not trying to determine Α. That's correct. 8 whether or not the TVT device was cytotoxic in vivo 8 Not a good laboratory practices Q. 9 in this study? 9 study, correct? 10 Any in vivo cytotoxicity related to 10 It should be differentiated from a TVT mesh would have been revealed during the conduct FDA GLP study, which is in compliance with federal 11 11 12 of this study in response to the purpose to the regulations. 13 study. 13 All other non-GLP studies conducted 14 Q. Another short-term study, correct, by 14 at Ethicon are done in the spirit of GLP and are 15 definition in the laboratory scientific community? 15 conducted in every manner like a GLP study, except for quality assurance unit oversight. 16 This is a short-term experiment. A. 16 17 17 There's the -- following of the same Then you have the 182 intramuscular 18 tissue reaction study in rats using polypropylene 18 SOPs, the same policies and procedures are applied, 19 mesh with Triclosan. 19 and the study is conducted as it would be under GLP 20 That was after that statement had 20 other than quality assurance unit oversight. 21 21 The next study you have listed there already been included in the IFU label, right? 22 After the statement -- after the 22 is a 28-day tissue reaction study of Prolene 23 statement that animal studies show the implantation 23 polypropylene mesh and autoclave Prolene polypropylene mesh implanted intramuscularly. We 24 of Prolene mesh elicits a minimal inflammatory reaction in tissue which is transient, right? That looked at that study yesterday. And that study,

8 (Pages 319 to 322)

	Page 323		Page 325
1	also a short-term study, showed up to a moderate	1	A. This would be considered relatively
2	inflammatory response, correct?	2	large pore size.
3	MR. THOMAS: Object to the form of	3	Q. Larger than the pores in the TVT,
4	the question.	4	correct?
5	THE WITNESS: Yes. It was up to	5	A. Yes.
6	moderate with an average of mild.	6	Q. A three-month preclinical trial to
7	BY MR. THORNBURGH:	7	assess the fixation force of a new TVT-X and a sheep
8	Q. It was mild to moderate, correct?	8	model. That was, I think, a 12-week study, right?
9	That was the summary in the study?	9	A. It says three months.
10	MR. THOMAS: Object to the form of	10	Tab Number 40.
11	the question.	11	Q. Yeah. It would be a short-term
12	THE WITNESS: I recall it was we	12	study, wouldn't it?
13	can check. I recall it was minimal to mild. Let me	13	A. That would be considered a subchronic
14	just look at that quickly.	14	or mid-term study.
15	Tab 36.	15	Q. Not a long-term study, correct?
16	In that summary, then, the reaction	16	A. That's correct.
17	was typical for implanted Prolene mesh and consisted	17	Q. And the primary endpoint in that
18	of an initial mild to moderate subacute inflammation	18 19	study was to look at the pullout force, correct?
19 20	which gradually changed with time into a minimal to	20	A. Let me just take a look at 40. I
21	moderate chronic form body reaction. BY MR. THORNBURGH:	21	think there were other endpoints.
22	Q. The histological evaluation in	22	Q. Right, but the primary endpoint was to look at the pullout force.
23	comparison to mechanical pullout strength of Prolene	23	A. Well, I'll confirm in a moment.
24	mesh and Prolene Soft mesh in a rabbit model.	24	Q. By the way, did you ever find the
25	That's dated 2002, right?	25	pathology report related to this study?
	Page 324		Page 326
,			
1	A. Yes.	1	MR. THOMAS: Object to the form of
2	Q. How many how many days or weeks	2	the question.
4	was that study? A. Let me confirm.	4	THE WITNESS: We're still looking for that.
5	That would be Tab 37.	5	BY MR. THORNBURGH:
6	That would be 140 37. That study was out to 14 days.	6	Q. Did you inquire about the lost slides
7	Implantation.	7	yesterday?
8	Q. So, clearly, a short-term study,	8	MR. THOMAS: Object to the form of
9	correct?	9	the question.
10	A. Yes.	10	THE WITNESS: No.
11	Q. You have a 90-day subchronic toxicity	11	BY MR. THORNBURGH:
12	study after intraperitoneal implantation of a	12	Q. Did you inquire with anybody whether
13	laminated composite composed of soft Prolene mesh	13	or not
14	PDS film and INTERCEED fabric.	14	A. Can I answer the question of a couple
15	That's not TVT mesh, is it?	15	ago, and then we can move forward?
16	A. No.	16	Q. Sure. I think my question was
17	Q. A 24-week intramuscular study in rats	17	MR. THOMAS: Excuse me. He's looking
18	comparing trilaminate prototype from Project Coyote	18	for the primary endpoint.
19	of soft Prolene polypropylene mesh, that's clearly	19	MR. THORNBURGH: I am trying to
20	not TVT, is it?	20	refresh his memory.
21	A. That's just another variant of	21	MR. THOMAS: If he he's looking
22	Prolene polypropylene mesh.	22	right now. If you want to ask him a different
23	Q. It's not TVT, is it?	23	question
23 24 25	Q. It's not TVT, is it?A. No.Q. What is the pore size?	23 24 25	MR. THORNBURGH: I was going to remind him that my question related to the primary

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Page 329 Page 327 1 That would be considered a short-term endpoint of the study, Dave. 1 study, correct? 2 MR. THOMAS: Please, Dan. This is 3 3 going to be a long day, and you're very contentious A. That would be a mid-term study. with the witness and with me this morning. I 4 Q. Not a long-term study, right? 5 5 understand we didn't end on the best of terms That's correct. A. 6 yesterday. Excuse me --How long does it take before mesh Q. 7 7 MR. THORNBURGH: I am being at my starts to contract? 8 best behavior right now. 8 MR. THOMAS: Object to the form of 9 9 MR. THOMAS: Well, please. Just slow the question; scope. down. Let the witness answer the question, and let 10 BY MR. THORNBURGH: 10 him finish his answer before you ask another one. 11 11 Are you prepared to answer that Q. That's what he's doing right now. 12 12 question today? 13 MR. THOMAS: Object to the form of 13 THE WITNESS: The aim of this 14 14 preclinical study was to evaluate less invasive TVT the question. 15 mesh, and then it goes on. 15 THE WITNESS: No -- because it 16 BY MR. THORNBURGH: 16 depends on a lot of factors. And if there are any 17 specific studies you want to talk about that are in Goes on to say what? MR. THOMAS: He's going to tell you, 18 18 the compilation of documents that we've provided, 19 Dan. I'd be glad to talk about those. 20 THE WITNESS: Studying the fixation 20 BY MR. THORNBURGH: 21 phase divided into three components. 21 Well, Ethicon studies showed that 22 Prolene mesh can shrink up to 30 to 50 percent, 22 And then -- yeah. So I would conclude that the primary objective is biomechanical 23 right? 23 with a histology component included. 24 MR. THOMAS: Object to the form of 25 BY MR. THORNBURGH: 25 the question; scope. Page 328 Page 330 What steps did you take yesterday to 1 Dan, that's not even on the 2 locate the pathology report? designations --3 MR. THOMAS: Object to the form of 3 BY MR. THORNBURGH: 4 4 Are you prepared to discuss that the question. 5 THE WITNESS: I did not take any 5 today, Doctor? б A. No. б steps. BY MR. THORNBURGH: 7 7 Q. Well, I mean, what is part of the 8 Did you make an inquiry to Joerg 8 designations is porosity studies. And that --Holste whether or not any of the meshes that were porosity studies, clearly, one of the things that explanted in that study showed encapsulation of the you can look at is mesh contraction. 10 10 mesh? 11 11 Did you look at any studies involving 12 12 A. mesh contraction --13 Q. Did you make an inquiry with anybody 13 MR. THOMAS: Object. 14 yesterday as to whether or not any of the slides 14 BY MR. THORNBURGH: were lost? 15 -- other than -- other than the one 15 MR. THOMAS: Object to the form of 16 that you have listed here? 16 17 17 the question. MR. THOMAS: Object to the form of 18 BY MR. THORNBURGH: 18 the question; scope. 19 19 During or -- during or after that THE WITNESS: This is one that we've 20 study was conducted? 20 conducted, Tab 41. 21 21 BY MR. THORNBURGH: A. No. 22 And in the next document you have 22 What mesh was involved in that case? Q. 23 listed here is an investigational study of Swine 23 A. I'll have to look at the detail. models to evaluate mesh contraction and tissue Let me just try to simplify. Was TVT 24 Q. 25 integration over a 13-week period. 25 mesh involved in that case?

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Page 331 Page 333 1 1 A. Let me confirm. No, it does indicate it is Prolene Α. 2 2 Q. Perhaps it was the heavyweight small Soft. Prolene Soft is one of the meshes that were 3 pore. evaluated. 4 MR. THOMAS: You've asked three 4 Q. What you can say for certain is that 5 questions. You haven't let him answer any of them 5 that mesh wasn't the Prolene mesh contained within 6 TVT? yet. Let him answer a question, please. 7 7 THE WITNESS: Three mesh implants I can't say that for certain, but I 8 were studied: Prolene mesh, Prolene Soft mesh, and 8 believe it is not. 9 9 ULTRAPRO mesh. You have the biocompatibility risk 10 Although it doesn't indicate the 10 assessment report for Proceed's surgical mesh. Is 11 11 version of Prolene mesh, the date of the study, that a large -- is that a lightweight large pore 6/21/07, would suggest that it's 5 mil flat mesh. 12 12 mesh? 13 13 BY MR. THORNBURGH: MR. THOMAS: Object to the form of Which is a different mil that is the question. 14 14 15 used -- different Prolene fiber size than is used in 15 BY MR. THORNBURGH: 16 16 the TVT Prolene mesh, correct? The Proceed? Q. 17 17 This would be Prolene Soft mesh. Α. Yes. Α. Do you know what the pore sizes are 18 18 Q. So it's a 3.5 lightweight mesh, 19 in that particular Prolene mesh that was studied? 19 correct? 20 MR. THOMAS: Object to form; asked 20 A. 21 and answered. 21 Q. Not the same mesh in TVT, correct? 22 22 THE WITNESS: I know that it's less A. That's correct. than the 6 mil TVT mesh. 23 Then you have the biocompatibility 23 24 BY MR. THORNBURGH: risk assessment report for the Gynecare TVT product 25 Does it say current production, family. That's -- that would be related to --Q. Page 332 Page 334 Prolene mesh? that's the TVT product, right? 1 2 2 A. No, it does not. A. Yes. 3 So you don't know sitting here today 3 So you would agree with me that the if that's the current production at the time or if vast majority of the documents that you listed in 5 that was some sort of prototype of the Prolene mesh, your list regarding the statement that Prolene mesh б elicits a minimal inflammatory reaction in tissue б do you? 7 MR. THOMAS: Object to the form of 7 which is transient, either were suture studies, not 8 the question. 8 mesh studies, short-term studies, not long-term 9 THE WITNESS: I think if it were a studies or mid term, not long-term studies, or prototype, it would indicate such. involved -- some of the studies involved meshes that 10 10 11 What I have in front of me is not 11 were large pore lightweight meshes, correct? sufficient to positively identify that was 5 mil 12 MR. THOMAS: Excuse me. Object to 12 mesh, but all the data points are in that direction. 13 the form of the question. 13 14 BY MR. THORNBURGH: 14 THE WITNESS: All of those studies 15 You can't tell from looking at that 15 are included in this list. if it's a 3.5 mil Prolene mesh, can you? BY MR. THORNBURGH: 16 16 MR. THOMAS: Object to the form of 17 17 Did you ever conduct a study or did 18 the question. 18 Ethicon ever conduct a study that looked at the 19 THE WITNESS: Yes, I can. 19 TVT -- strike that. 20 BY MR. THORNBURGH: 20 Did Ethicon ever conduct a study that How can you tell? looked at the Prolene mesh in the TVT and compare it 21 Q. 22 Because that would be Prolene Soft 22 to a negative control to determine the inflammatory A. response in TVT? 23 mesh. 23 24 24 And it doesn't indicate it's Prolene A. No. That would not be so useful. 25 Soft. Is that what you're saying? You -- ULTRAPRO was compared to

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Page 335 Page 337 1 THE VIDEOGRAPHER: We're now going Prolene, wasn't it? 1 2 2 MR. THOMAS: Object to the form of off the video record. It's now 9:45. 3 3 (Short break.) the question; scope. 4 4 THE WITNESS: In the study that I (Whereupon, the court reporter read 5 5 back the requested portion of the record.) just mentioned, yes. 6 6 BY MR. THORNBURGH: THE VIDEOGRAPHER: Back on the video 7 7 Well, do you recall -- do you recall record, 9:56. 8 doing a study that looked at --8 THE WITNESS: Now, it's my 9 9 I just want to clarify which study understanding that the literature search results that was, because we've been talking about a lot of from the two literature searches conducted have been 10 11 provided to the plaintiff's counsel. That includes 11 studies. 12 That would be Tab 42. 12 all the studies in their entirety that came from 13 13 Q. Can you read off the name of that that literature search of RDCS. 14 BY MR. THORNBURGH: 14 study for me? 15 An investigational study of Swine 15 Is that list larger than the list models to evaluate mesh contraction and tissue in 16 that you provided in Exhibit 2241? 16 growth over a 13-week period. 17 MR. THOMAS: Those are the lists of 17 the gross searches that were provided from 1960 to 18 I misspoke. 18 19 It's the same study, but the study 19 1980 and then the two searches from 1980 to 2000. 20 that I intended to call out was Tab 41. 20 Those are the lists that we're talking about. 21 Tab 42 is simply the pathology report 21 MR. THORNBURGH: I am asking the 22 22 for that study. witness. 23 23 Do you recall doing a study that MR. THOMAS: That's fine. 24 looked at the tissue response to ULTRAPRO and 24 THE WITNESS: Could you repeat? compared it to the old construction heavyweight 25 BY MR. THORNBURGH: Page 336 Page 338 Prolene and found that the tissue response was --1 Yes. Is there a larger list of 2 there's a greater inflammatory response with the old studies than is contained in your section regarding 3 construction 6 mil Prolene compared to the ULTRAPRO? 3 the minimal and transient inflammatory response? 4 MR. THOMAS: Object to the form of 4 A. Yes, there is a larger list, as I've 5 5 the question. described. THE WITNESS: I don't believe so. б 6 From those two literature searches, 7 BY MR. THORNBURGH: 7 studies were obtained from R&D central file, which were felt to be relevant to each of the topics under 8 Do you know if that study was ever 8 9 conducted? 9 discussion. MR. THOMAS: Object to the form of 10 Some of those studies turned out not 10 the question. 11 to be relevant. Those studies that were determined 11 12 THE WITNESS: I am not aware of such to be relevant to each of the topics for discussion 13 a study. It's not a study that we provided. were then compiled for this particular topic. You BY MR. THORNBURGH: 14 14 see this list of 44 documents. 15 Like we talked about yesterday when 15 Now, if there was a study that looked we talked about the porosity studies, was there a at and compared ULTRAPRO, which is a lightweight 16 larger list that was created by you or someone else large pore mesh, to Prolene 6 mil mesh, that study 17 17 18 which contained more studies that are currently 18 did not make it onto your list, did it? listed in this section regarding the studies related 19 It would have fallen out of the 19 20 to the statement that the inflammatory response is 20 original R&D central file search, and it would have 21 minimal and transient? 21 been included in this list, because it would have 22 MR. THOMAS: I'm sorry. Object to 22 contained TVT mesh, even though it's a comparison to the form of the question. I'm trying to go with my 23 some other mesh. screen and I've lost my --24 So that would have definitely been 24 (Brief interruption.) 25 relevant. 25

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Page 339 Page 341 1 You don't see any study on this list mesh in TVT would elicit a minimal transient Q. 2 inflammatory response, right? that you provided -- strike that. 3 You chose what documents -- what 3 That 1973 study needs to be 4 4 studies would be listed in your IFU list of studies considered in context with the NDAs for Prolene 5 that support the claim that the inflammatory 5 suture, where long-term studies were conducted two response is minimal and transient, right? years in rat, three years in dog, three months in 7 7 A. Yes. rabbits, looking at the same polypropylene --8 Q. And nowhere on that list is a study Prolene polypropylene fiber that's used in Prolene 9 9 that compared ULTRAPRO to Prolene and found that mesh. ULTRAPRO elicited a more minimal inflammatory 10 It's the leveraging of those 10 11 long-term studies and the 1973 study, which is 11 response, correct? 12 That is not on this list, and I am 12 relatively short term as you point out, forms the A. basis for the information provided by preclinical to 13 not aware of such a study. That would have been a relevant study 14 the folks that prepare the IFU. 14 15 to include on this list if it existed, correct? 15 MR. THORNBURGH: Move to strike; 16 16 MR. THOMAS: Object to the form of nonresponsive. 17 BY MR. THORNBURGH: the question. THE WITNESS: Yes. 18 18 In that list -- in fact, in this BY MR. THORNBURGH: 19 19 entire list of 43 studies, 44 studies, that is the 20 That would have been a relevant study 20 only Prolene mesh study that formed the basis for 21 to do to compare the difference in inflammatory the claim in the IFU that the Prolene and TVT will 22 response of a lightweight large pore mesh to TVT, elicit a minimal transient inflammatory response, 23 2.3 correct? correct? 24 MR. THOMAS: Object to the form of 24 MR. THOMAS: Object to the form of 25 the question. 25 the question; scope. Page 340 Page 342 THE WITNESS: I don't believe the THE WITNESS: Yes, it would have been 1 a relevant study. results from the 1973 Prolene mesh study that went 2 3 BY MR. THORNBURGH: 3 for 28 days can be assessed without considering the 4 Of the 44 studies that made it onto 4 long-term results from the Prolene suture studies your final list to support the claim that TVT documented in the Prolene suture NDA. elicits a minimal transitory inflammatory response, б MR. THORNBURGH: Move to strike; б 7 31 of those studies are suture studies, correct? 7 nonresponsive. 8 A. I accept your count. 8 BY MR. THORNBURGH: 9 Q. Well, Tab 1 through Tab 31, correct? 9 Answer my question, please. I've not been keeping track. 10 MR. THOMAS: He did answer your 10 A. And of the 13 studies involving 11 Q. 11 question. 12 BY MR. THORNBURGH: 12 mesh --My question is: In this list of 43 13 A. Excuse me. Just for clarification, I 13 14 was just scanning the 1 through 31, and I see that 14 studies -- 44 studies, the short-term 28-day study Number 10 is, in fact, a 1973 study with Prolene 15 from 1973 was the only Prolene mesh study that 15 mesh. It's the same mesh. formed the basis for the claim in the IFU that the 16 Prolene in TVT will elicit a minimal transitory Oh, I'm sorry. Correct. 17 17 Q. 18 So of the first 31 studies, only one 18 inflammatory response. Correct? involved Prolene mesh, correct? 19 Yes. A. 19 20 A. Yes. 20 Q. Of the 13 mesh studies contained 21 21 And that one study in the first 31 within your IFU list of studies that support the 22 was a short-term study, correct? 22 claim that Prolene mesh in TVT elicits a minimal 23 A. Yes. transient inflammatory response, approximately 12 of And that's the study that formed the 24 those were either short-term or mid-duration 24 25 studies, correct? 25 basis of the language in the IFU that the Prolene

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Page 343 Page 345 1 MR. THOMAS: Object to the form of start over again. I have the right one now. 2 the question. The designation made by plaintiffs 3 3 states, Paragraph 3: The identity of, the location THE WITNESS: I accept your count. 4 BY MR. THORNBURGH: 4 of, and the substance of any and all studies, data, 5 5 and/or other evidence that form the basis of the You also have been designated as the person most knowledgeable regarding preclinical or following claim/statement included in the attached 7 7 animal studies that support the claim in the IFU instructions for use for the TVT products. The 8 that the material is not absorbed, nor is it subject 8 material is not absorbed, nor is it subject to 9 9 to degradation or weakening by the action of tissue degradation or weakening by the action of tissue enzymes, correct? 10 10 enzymes. 11 11 A. That's correct. That's the designation. MR. THOMAS: Object to the form of 12 12 BY MR. THORNBURGH: 13 13 the question. So you've been designated as the 14 I think if you look at the topic that 14 person most knowledgeable regarding studies or 15 he was identified on, it was a single sentence. And 15 evidence that support the claim in the IFU that the that is the scope of the designation. 16 Prolene mesh in TVT is not absorbed, nor is it 16 17 THE WITNESS: Well, I stand subject to degradation or weakening by the action of 18 18 corrected. I have in front of me a compilation of tissue enzymes. Correct? 19 studies that address a topic for discussion, and 19 A. Yes. 20 that topic indicates -- and I quote: The material 20 Q. In other words, the claim by Ethicon 21 is not absorbed, nor is it subject to degradation or 21 in the IFU is that the Prolene mesh in the TVT will 22 weakening by the action of tissue enzymes. End not degrade, correct? 23 23 quote. MR. THOMAS: Object to the form of 24 BY MR. THORNBURGH: 24 the question. 25 Which is the exact question I asked. 25 THE WITNESS: It says that it's not Page 344 Page 346 MR. THOMAS: I don't think you did. absorbed, nor is it subject to degradation or 2 weakening by the action of tissue enzymes. BY MR. THORNBURGH: 3 Q. Let me ask it again. I'll read from 3 BY MR. THORNBURGH: 4 the transcript. 4 Is it Ethicon's position that the 5 You also have been designated as the studies and evidence support the claim that the person most knowledgeable regarding preclinical or Prolene mesh in TVT will not degrade? б б 7 7 animal studies that support the claim in the IFU MR. THOMAS: Object to the form of that the material is not absorbed, nor is it subject 8 the question. 9 to degradation or weakening by action of tissue 9 THE WITNESS: In a general sense. BY MR. THORNBURGH: 10 enzymes. 10 11 11 What do you mean by "in a general Correct? Q. sense"? 12 12 MR. THOMAS: Object to the form of the question. That's not the designation. 13 A. Well, that statement is different 13 14 The designation is and it reads 14 from the statement that's in the IFU. 15 verbatim in terms that you've written: The identity 15 Part of the statement is that the Q. of, the location of, and the substance of any and Prolene mesh in the TVT will not degrade, right, by 16 16 all studies, data, and/or evidence that form the 17 17 the tissue enzymes in the human body. Correct? 18 basis of the following claim/statement contained in 18 A. Yes. 19 the attached instructions for use for the TVT Is that Ethicon's position? 19 Q. 20 products. Animal studies show that implementation 20 A. Yes. of Prolene mesh elicits a minimal inflammatory --21 Is it Ethicon's position that the 22 Prolene in the TVT is subject to degradation under 22 I'm sorry. 23 MR. THORNBURGH: You're looking at 23 certain conditions? MR. THOMAS: Object to the form of 24 the wrong designation. 24 MR. THOMAS: Okay. I am. Let me 25 the question. 25

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Page 347 Page 349 THE WITNESS: That's not what this 1 1 MR. THOMAS: Excuse me. I need to 2 says. take a very quick break. 3 3 BY MR. THORNBURGH: THE VIDEOGRAPHER: 10:16, off the 4 Well, is it Ethicon's position that 4 video record. 5 the Prolene mesh will degrade under certain -- in 5 (Short break.) 6 THE VIDEOGRAPHER: Back on the video certain environments? 7 MR. THOMAS: Object to the form of 7 record, 10:20. 8 the question. 8 BY MR. THORNBURGH: 9 9 THE WITNESS: It's Ethicon's Doctor, you would agree that the position, as outlined in these two folders that 10 human body, due to the presence of O2 in various 10 contain 49 different studies, that the material in 11 forms, is a potentially powerful oxidizer? 11 MR. THOMAS: Object to the form of TVT mesh, which is Prolene polypropylene, is not 12 12 13 the question; scope. 13 absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. 14 THE WITNESS: They can't be too -- I 14 15 BY MR. THORNBURGH: 15 would agree in general, but they can't be too powerful, because too powerful would be incompatible 16 Now, you agree with me that Ethicon 16 has conducted studies which have shown that in vivo, with life. 17 BY MR. THORNBURGH: in the human body, or in animal studies, the Prolene 18 18 19 mesh does, in fact, suffer from surface cracking on 19 Q. Powerful enough to degrade 20 the outer layer of the mesh? 20 polypropylene, right? 21 21 MR. THOMAS: Object to the form of MR. THOMAS: Object to the form of 22 the question. 22 the question. 23 23 THE WITNESS: You're making reference THE WITNESS: That would need to be 24 to surface changes observed in a seven-year dog 24 determined. 25 study? 25 BY MR. THORNBURGH: Page 348 Page 350 BY MR. THORNBURGH: 1 Well, let me look at a document I 2 No, there's more than that, but we'll believe you had listed on your list of evidence. Q. MR. THORNBURGH: We'll mark it as 3 talk about the dog study. 3 4 But you agree that there have been 4 Exhibit 2250. ETH.MESH.10575391. studies conducted at Ethicon that show degradation 5 (Document marked for identification 5 of the surface layer of the Prolene mesh? as Exhibit T-2250.) б б 7 7 MR. THOMAS: Object to the form of BY MR. THORNBURGH: 8 the question. 8 This is Critical Reviews in Q. 9 THE WITNESS: I only know of one 9 Biocompatibility. You've seen this? study looking at surface changes in Prolene suture. 10 10 A. Yes. That would be the seven-year dog study. 11 Q. Before, right? 11 And that would be -- that would be 12 12 A. Tab 33, seven-year data for ten-year Prolene study. 13 Q. It appears that the authors of this 13 14 ERF 85-219 1992. 14 document is -- C.C. Chu? BY MR. THORNBURGH: 15 A. 15 Did you look at the five-year data? Q. And the referee is Postlethwait. Am I 16 Q. 16 Yes, as part -- well, the five-year pronouncing his name correctly? 17 17 18 endpoints were part of this study. 18 I am not certain. I don't know him. MR. THOMAS: Just for the record, That sounds good to me. 19 19 20 that tab has been supplemented by this additional 20 Q. Do you know Dr. Chu? 21 disclosure. I'll make sure the witness has that I've met him once. 21 A. 22 available to him. 22 Okay. And the title of this document Q. 23 THE WITNESS: If we need to talk 23 is the degradation of biocompatibility -- I'm sorry. 24 about the seven-year dog study, this would be the 24 Strike that. 25 25 one to -- to discuss. The degradation of -- strike that.

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Page 351 Page 353 1 The title of this, what appears to be chance to review this before today, right? a book or a chapter in a book, is the degradation 2 I've read through this document at of -- "The Degradation And Biocompatibility Of 3 one point. 4 Suture Material," right? 4 Q. The authors here in this paragraph 5 A. Yes. 5 are talking about polypropylene, right? 6 6 Where does this come from? What's MR. THOMAS: Which paragraph are you Q. 7 7 the critical reviews and biocompatibility; do you talking about? 8 know? 8 MR. THORNBURGH: I'm sorry. The 9 9 Well, I've seen critical reviews in third paragraph on Page 288, Bates number ending in toxicology before. I think this is an attempt by 10 5419. 10 CRC press to put forward review articles by experts, THE WITNESS: They're talking about 11 11 considered experts in the field, that would 12 polyethylene sutures of which polypropylene is one. 12 13 BY MR. THORNBURGH: 13 summarize what is known about a particular topic up 14 14 to a certain point in time. Okay. And in the highlighted 15 Q. And this is 1985, right? 15 section, the authors write: Although this class of 16 16 polymer is resistant to hydrolysis, it is A. 17 This is before the TVT was marketed, susceptible to oxidative degradation. Oxidation is Q. not as well known as hydrolysis in biomedical 18 correct? polymers in 1985. The human body, due to the 19 A. Yes. 20 In fact, it's before the TVT was 20 presence of O2 in various forms, is a potentially Q. 21 designed and developed, correct? 21 powerful oxidizer. 22 22 Liebert and others examine the rate A. Yes. 23 Q. 23 of oxidation of polypropylene fibers with and Do you find this to be authoritative? 24 A. Up to 1985, yes. I think it reflects without antioxidants implanted subcutaneously in 25 what was generally known to be so in the field. hamsters. They found that the pure fiber without Page 352 Page 354 And this document was -- if you look, antioxidants degraded by an oxidative mechanism there's an ETH.MESH. number on it, which would 2 similar to high temperature autooxidation. 3 indicate that this document was within the files at 3 The degradation began to occur after 4 Ethicon, correct? 4 only about ten days, and this initiation period 5 Yes. I believe it's in -- here as 5 lasted about 108 days. Tab 22 in the IFU three-folder. б The degradation product -- do you б 7 MR. THOMAS: Object to the form of 7 know what that -- what that means right here, C 8 8 equals O? the question. 9 BY MR. THORNBURGH: 9 A. It is a carbonyl group. How did you find this document which 10 So: The degradation product, the 10 Q. made it to your list of supporting evidence carbonyl group, was observed in the form after 11 11 99 days of implantation. Whether this observation regarding the claim in the IFU that the Prolene TVT does not degrade by the actions of enzymes in the 13 is applicable to polypropylene suture material is 13 14 human body? 14 not known and needs to be further studied. 15 A. It was one of the references that FDA 15 Do you see that? provided when they reclassified Prolene 16 Yes. 16 A. polypropylene suture from Class 3 to Class 2. 17 17 Q. How many studies are you aware of 18 And I think I -- yes. And that would 18 that Ethicon did to determine if the Prolene in TVT be Tab 28 in the folder, IFU 3, entitled "FDA can degrade as a result of or including as a result 19 19 Reclassification Of Prolene Polypropylene 20 of oxidation in vivo inside the body? 20 Non-Absorbable Sutures, October 12, 1990." 21 21 There are roughly -- well, there 22 Now, the authors -- turn with me to 22 are -- there are 49 documents in these two -- two 23 Page 288 of the critical reviews. binders labeled IFU 3 that support the statement The ETH.MESH. number is 10575419. that's the subject matter topic that the material is 24 25 The authors are -- you've had a not absorbed, nor is it subject to degradation or

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Page 355 Page 357 weakening by the action of tissue enzymes. crystalline regions offering the most strength of a 1 2 2 fiber compared to the amorphous regions. How many preclinical studies were 3 3 done that looked at the primary endpoint degradation BY MR. THORNBURGH: 4 of the Prolene fiber in TVT? 4 One way of looking for degradation of 5 MR. THOMAS: Object to the form of 5 Prolene would be through FTIR analysis, correct? 6 6 the question. MR. THOMAS: Object to the form of 7 7 THE WITNESS: Every study where TVT the question; scope. 8 was implanted, there is an opportunity to assess 8 THE WITNESS: That could be a way, 9 9 whether or not there's any degradation of the and, more likely, IR microspectroscopy, where there filaments and any resulting effects from that. 10 is a very specific focus on areas of interest. 10 11 11 BY MR. THORNBURGH: But, again, that's an analytical 12 12 chemistry kind of area. Although I have some What types of -- what types of tests are performed to determine degradation of polymer understanding of it, depending on how much detail 13 14 filaments? you would need, I may or may not be able to help. 15 A. The key endpoints to make a 15 BY MR. THORNBURGH: 16 16 determination as to whether or not a material fiber And you're not at least prepared would be degraded would be to look at quantitative 17 17 today to talk about carbonyl bands that show up on 18 parameters, like molecular weight and, perhaps most 18 FTIR microscopy which would indicate oxidation of 19 importantly, tensile strength. 19 the Prolene fibers, correct? 20 In the absence of loss of molecular 20 That's right. I do not have enough A. 21 21 weight and in the absence of a loss in tensile depth in that area. 22 strength, one cannot conclude that there's been any Another way of analyzing degradation 23 23 impact or degradation on a fiber. of a polypropylene like Prolene would be to look at 24 Do you know what I mean by when I say melting point, right? 25 amorphous zones or amorphous regions of the Prolene 25 Again, that's -- that's a polymer Page 356 Page 358 1 fiber? chemistry kind of term, and I'm not prepared to 2 2 A. I have a general understanding. address any melting point endpoints. 3 Q. What is your understanding of 3 Do you know -- do you know generally amorphous zones or amorphous regions of the Prolene 4 what I mean by melting point? 5 5 fiber? MR. THOMAS: Object to the form of б 6 MR. THOMAS: Object to the form; the question. 7 7 scope. THE WITNESS: It's the point -- it's 8 8 THE WITNESS: They're not the temperature at which a substance melts. crystalline, and they do not offer much contribution 9 BY MR. THORNBURGH: in the way of tensile strength. 10 10 Did you look at any -- before you BY MR. THORNBURGH: 11 came in today, did you look at any studies that were 11 12 12 They're less stable than the conducted by Ethicon that looked at the melting 13 crystalline bulk Prolene, correct? 13 point of pieces of the outer surface of Prolene mesh 14 MR. THOMAS: Object to form; scope. which, when the study was conducted, showed evidence 15 THE WITNESS: They're different areas 15 of oxidation of the polypropylene? of the polymer. 16 MR. THOMAS: Object to the form of 16 17 BY MR. THORNBURGH: 17 the question. 18 Less stable areas of the polymer? 18 THE WITNESS: I've not reviewed any 19 19 MR. THOMAS: Excuse me. Do you want melting point data. 20 him to answer your question? 20 BY MR. THORNBURGH: THE WITNESS: I don't know that I 21 21 And in any event, these authors write 22 22 would characterize it as less stable. That might be that the human body is potentially a powerful a question for a polymer chemist. But, clearly, 23 oxidizer, right? 24 there are differences in mechanical characteristics 24 A. It's as it's stated. 25 25 between amorphous and crystalline regions, the Q. And there's a discussion about a

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Page 359 Page 361 BY MR. THORNBURGH: study by Liebert. Did you read the Liebert study 1 before you came here today? 2 And could you explain to the ladies 3 3 A. I am looking for it right now. Give and gentlemen of the jury what we mean by "leach"? 4 4 me a moment to go through this list. Leaching means the movement of 5 I don't see it in this list, but I 5 substances from an implant into the surrounding 6 have reviewed that publication. tissue. 7 7 And you're familiar, then, in the Q. 8 Liebert study that when Liebert and his fellow 8 MR. THOMAS: While you're doing this, 9 9 investigators examined the rate of oxidation of are you going to ask him questions about the polypropylene fibers, they found degradation in 10 leaching notebooks? 10 animal study -- in animal studies of the 11 MR. THORNBURGH: Not yet. We will be 11 polypropylene fibers which did not contain 12 12 asking questions about leaching. 13 13 antioxidants, correct? MR. THOMAS: We'll put them away, 14 14 A. That's correct, as reflected by C.C. then. 15 Chu in this review article, when he says they found 15 BY MR. THORNBURGH: 16 that the pure fiber (without antioxidant) degraded You've seen the Sunoco material 16 by an oxidation mechanism similar to high 17 safety data sheet previously, haven't you? 17 18 MR. THOMAS: Object to the form of 18 temperature autooxidation. 19 What he doesn't say here and what is 19 the question. 20 called out in the Liebert paper is that the fiber 20 I think this was covered at length in 21 with antioxidant did not show any evidence of 21 his prior deposition. 22 THE WITNESS: I think you showed this 22 degradation. 23 23 to me at the last deposition. Right. And one of the topics that 24 you've been designated to discuss is leaching, BY MR. THORNBURGH: 25 right? 25 Right. And this has been premarked Page 360 Page 362 1 A. Yes. as Exhibit Number T-2111. 2 2 Now, if you turn with me to --Q. And some of the studies that you looked at showed that the antioxidants, Santonox R 3 Well, do you have an understanding and Lubrol, can leach out of the Prolene fiber, 4 that this is the same Prolene homopolymer as 5 5 correct? contained within the TVT Prolene? 6 б MR. THOMAS: Object to the form of A. Let me take a look at the... 7 7 Q. You don't recall that off the top of the question; scope. 8 8 your head? THE WITNESS: Yeah. It's not the 9 I'd rather pull the folder and be original supplier, but those suppliers may have A. able to give you a more complete answer. 10 changed. It may be the current supplier. I don't 10 This is a folder that contains --11 11 know that for certain, but if you -- if you say that MR. THOMAS: There are three of them. 12 this -- this is the source of the polypropylene 12 13 BY MR. THORNBURGH: resin for polypropylene-based products, I would not 13 14 Q. Let me ask you this question real 14 disagree. quick. 15 BY MR. THORNBURGH: 15 Let me finish your other. 16 And Sunoco is a petro oil company, 16 A. Well, I'm going to withdraw the 17 correct? Are you familiar with that? 17 18 original question. I'm going to try to streamline 18 Yes. Yes. It's Sun Oil company. 19 19 these. If you turn with me to the fourth 20 Is it Ethicon's position that the 20 page, which is ETH.MESH.02026594, you would agree antioxidants in the polypropylene Prolene fibers in with me that this MSDS for polypropylene resin shows TVT can leach from the fibers? 22 that -- under the incompatibility, that the 22 23 MR. THOMAS: Object to the form of following materials are incompatible with the product: Strong oxidizers, such as chlorine, 24 the question. 25 THE WITNESS: Yes. peroxide, chromates, nitric acid, perchlorates,

18 (Pages 359 to 362)

Page 363 Page 365 concentrated oxygen, sodium hypochlorite, calcium one before that. hypochlorite, and chlorine and nitric acid, correct? 2 That answer is yes. There are two 3 3 Yes. A. folders --4 MR. THOMAS: You left out 4 MR. THOMAS: Excuse me. Let him 5 5 permanganates. answer the question. BY MR. THORNBURGH: BY MR. THORNBURGH: 7 7 My question was: Did you Permanganates, chlorine, and nitric Q. 8 acid, correct? 8 personally --9 9 A. Yes. That's the list. No. Your question was on behalf of 10 And you would agree with me that 10 Ethicon. 11 11 according to the evidence that you reviewed in Did you personally? preparing for this 30(b)(6) deposition, that the 12 MR. THOMAS: Okay. Stop. Let's 12 13 start over. And you ask a question that he can human body, as a result of the inflammatory response to foreign objects or foreign materials, can create 14 answer. You have five pending. 14 15 strong oxidizers in the body? 15 BY MR. THORNBURGH: MR. THOMAS: Object to the form of 16 16 Did you personally conduct any 17 17 studies that had the primary endpoint of looking at the question. 18 18 THE WITNESS: Strong is a relative degradation in animal studies? 19 term. But I believe that the strong oxidizers as 19 MR. THOMAS: Object to the form of 20 called out in this MSDS, that would make -- that 20 the question. 21 would be incompatible with polypropylene would not 21 THE WITNESS: Well, I understood I be biocompatible in the body. 22 was here to talk on behalf of Ethicon and not myself 23 BY MR. THORNBURGH: 23 personally. 24 Q. Well, according to Exhibit 24 MR. THOMAS: You can answer the 25 Number 2250, which you listed on your list of question. Did you personally do that? Page 364 Page 366 1 evidence supporting your claims, the authors wrote THE VIDEOGRAPHER: It's 10:44. We're that the human body, due to the presence of O2 in going off the video record. 2 3 various forms, is a potential powerful oxidizer. 3 This concludes Volume 2, Tape 1 of 4 Correct? 4 the videotape deposition of Dr. Thomas A. Barbolt. 5 5 (Short break.) Again, in my opinion, they're not as 6 THE VIDEOGRAPHER: We're now back on strong chemically as these oxidizers called out in 6 7 the video record. It's 10:52. 7 this MSDS that would not be compatible with polypropylene fiber or polypropylene material. 8 This begins Volume 2, Tape 2 of the 9 These oxidizers are not 9 videotape deposition of Dr. Thomas A. Barbolt. biocompatible. They are corrosive. They would not 10 MR. THOMAS: There was a question 10 be compatible with tissue. 11 pending. Do you want him to answer it? 11 Well, have you ever personally 12 12 MR. THORNBURGH: I thought he did studied -- have you personally studied -- strike 13 answer it. 13 14 that. 14 BY MR. THORNBURGH: 15 15 Have you -- on behalf of Ethicon, did Q. Were you not finished answering my question? you do any in vivo animal studies to look at, as a 16 16 17 17 primary endpoint, degradation? A. I don't think so. Could you repeat? 18 MR. THOMAS: Object to the form of 18 It's not on the... 19 MR. THOMAS: I don't think he the question; scope. 19 20 BY MR. THORNBURGH: 20 answered it. 21 21 Do you know sitting here right now The question appears at Line 63, 23. 22 BY MR. THORNBURGH: 22 whether or not you ever did such a study? 23 MR. THOMAS: Which question do you 23 Did you personally conduct any studies that had the primary endpoint of looking at 24 want him to ask --25 THE WITNESS: Well, I'll answer the degradation in your animal studies?

19 (Pages 363 to 366)

1 MR. THOMAS: Object to the form of 2 the question. 3 THE WITNESS: All implantation 4 studies that I have conducted and you have seen 5 my name on a number of them in the compilation of 6 data that we provided looking at degradation of the 7 implant is part of every implantation study. So 8 the answer is yes. 9 BY MR. THORNBURGH: 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 18 A. No. 19 BY MR. THORNBURGH: 19 you should conduct animal studies with endpoint of degradation? 10 THE WITNESS: I don't unctivation to deustion. In what context? 10 Q. Do you recall being told or strike that. 10 Provided the question of the or strike that. 11 MR. THORNBURGH: 12 Do you recall inquiring about provided to degradation? 13 THE WITNESS: Being told such studies? 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No. 18 MR. THOMAS: Object to the question; scope. 19 Strike that. 10 Provided the question. 10 Provided question. 11 MR. THORNBURGH: 12 Do you recall inquiring about provided to degradation? 13 THE WITNESS: Being told such studies? 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	derstand the
the question. THE WITNESS: All implantation studies that I have conducted and you have seen my name on a number of them in the compilation of data that we provided looking at degradation of the minplant is part of every implantation study. So the answer is yes. BY MR. THORNBURGH: Q. Do you recall being told is strike that. Do you recall inquiring about you should conduct animal studies with endpoint of degradation? A. No. Q. Did you do FTIR analysis? A. Is this on behalf of Ethicon or THE WITNESS: I don't und question. BY MR. THORNBURGH: Q. Do you recall inquiring about you should conduct animal studies with endpoint of degradation? THE WITNESS: Being told such studies? THE WITNESS: Being told such such such such such such such such	derstand the
THE WITNESS: All implantation 4 studies that I have conducted and you have seen 5 my name on a number of them in the compilation of 6 data that we provided looking at degradation of the 7 implant is part of every implantation study. So 8 the answer is yes. 9 BY MR. THORNBURGH: 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 THE WITNESS: I don't und 4 question. In what context? 5 BY MR. THORNBURGH: 6 Q. Do you recall being told or 7 strike that. 8 Do you recall inquiring about 9 you should conduct animal studies with 10 endpoint of degradation? 11 MR. THOMAS: Object to the 12 the question; scope. 13 THE WITNESS: I don't und 4 question. In what context? 5 BY MR. THORNBURGH: 6 Q. Do you recall inquiring about 9 you should conduct animal studies with 10 endpoint of degradation? 11 MR. THOMAS: Object to the 12 the question; scope. 13 THE WITNESS: I don't und 4 question. In what context? 5 BY MR. THORNBURGH: 6 Q. Do you recall inquiring about 10 endpoint of degradation? 11 MR. THOMAS: Object to the 12 the question; scope. 13 THE WITNESS: Being told 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	
 studies that I have conducted and you have seen my name on a number of them in the compilation of data that we provided looking at degradation of the implant is part of every implantation study. So the answer is yes. BY MR. THORNBURGH: Q. Did you do SEM EDX analysis? A. No. Q. Did you do FTIR analysis? A. Is this on behalf of Ethicon or personally? Q. Did you personally? A. No. Q. Did you do melting point analysis? A. No. Q. Did you do melting point analysis? A. No. 	
5 my name on a number of them in the compilation of 6 data that we provided looking at degradation of the 7 implant is part of every implantation study. So 8 the answer is yes. 9 BY MR. THORNBURGH: 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 18 A. No. 19 BY MR. THORNBURGH: 6 Q. Do you recall being told or 7 strike that. 8 Do you recall inquiring about endpoint of degradation? 10 endpoint of degradation? 11 MR. THOMAS: Object to the question; scope. 12 the question; scope. 13 THE WITNESS: Being told such studies? 15 BY MR. THORNBURGH: 10 Q. Did you personally? 11 A. No. 12 Q. Did you personally? 13 THE WITNESS: Being told such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	do you
data that we provided looking at degradation of the implant is part of every implantation study. So the answer is yes. BY MR. THORNBURGH: Q. Did you do SEM EDX analysis? A. No. Q. Did you do FTIR analysis? A. Is this on behalf of Ethicon or personally? Q. Did you personally? Q. Did you personally? Q. Did you personally? A. No.	do you
7 implant is part of every implantation study. So 8 the answer is yes. 9 BY MR. THORNBURGH: 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 18 Do you recall inquiring about you should conduct animal studies with the endpoint of degradation? 10 endpoint of degradation? 11 MR. THOMAS: Object to the question; scope. 12 the question; scope. 13 THE WITNESS: Being told such studies? 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	uo you
8 the answer is yes. 9 BY MR. THORNBURGH: 9 you should conduct animal studies with a personally? 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 18 Do you recall inquiring about 9 you should conduct animal studies with 2 endpoint of degradation? 10 endpoint of degradation? 11 MR. THOMAS: Object to the question; scope. 12 the question; scope. 13 THE WITNESS: Being told 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	•
9 you should conduct animal studies with 10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 19 you should conduct animal studies with 20 endpoint of degradation? 10 endpoint of degradation? 11 MR. THOMAS: Object to the question; scope. 12 the question; scope. 13 THE WITNESS: Being told 21 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	ıt syhathar
10 Q. Did you do SEM EDX analysis? 11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 10 endpoint of degradation? 11 MR. THOMAS: Object to the question; scope. 12 the question; scope. 13 THE WITNESS: Being told such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	
11 A. No. 12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 11 MR. THOMAS: Object to the question; scope. 13 THE WITNESS: Being told such studies? 14 such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 Q. Did you do melting point analysis? 17 A. No.	in the primary
12 Q. Did you do FTIR analysis? 13 A. Is this on behalf of Ethicon or 14 personally? 15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 12 the question; scope. 13 THE WITNESS: Being told such studies? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	he form of
13A. Is this on behalf of Ethicon or13THE WITNESS: Being told14personally?14such studies?15Q. Did you personally?15BY MR. THORNBURGH:16A. No.16Q. Yes.17Q. Did you do melting point analysis?17A. No.	
14 personally?14 such studies?15 Q. Did you personally?15 BY MR. THORNBURGH:16 A. No.16 Q. Yes.17 Q. Did you do melting point analysis?17 A. No.	I not to do
15 Q. Did you personally? 16 A. No. 17 Q. Did you do melting point analysis? 15 BY MR. THORNBURGH: 16 Q. Yes. 17 A. No.	I Hot to do
16 A. No. 17 Q. Did you do melting point analysis? 18 Q. Yes. 19 A. No.	
Q. Did you do melting point analysis? 17 A. No.	
MR. THOMAS: Object to the form of 18 Q. Do you know who Dr. Ram	nchaw ic?
	isliaw is:
19 the question. 19 A. Dr.? 20 THE WITNESS: No. 20 Q. Ramshaw?	
21 BY MR. THORNBURGH: 21 A. No, I do not.	
	Iniversity of
Q. So, clearly, the primary endpoint in 22 Q. Bruce Ramshaw from the U 23 the studies that you conducted were not oxidation or 23 Missouri?	Jiiiveisity of
24 degradation studies, correct? 24 A. I don't think we've met.	
25 MR. THOMAS: Object to the form of 25 Q. My question was: Do you I	know of him?
Page 368	Page 370
	rage 370
1 the question. 1 A. No.	
2 THE WITNESS: They were not oxidation 2 Q. I've handed what's been prem	iarked as
3 studies, but they definitely were degradation 3 Exhibit Number T-4012.	5500102
4 studies. That is a primary endpoint for any 4 The ETH.MESH. number is 0.	
5 implantation study of absorbable or non-absorbable 5 Now, if you go to the last page	
6 implants. 6 this e-mail, which would be the first e-r	
7 BY MR. THORNBURGH: 7 e-mail string, you write to Dr. Thomas I	
8 Q. Did you do SEM analysis? 8 Do you know who Dr. Thoma	.S DIVIIIO
9 MR. THOMAS: Object to the form of 9 is?	
10 the question. 10 A. Thomas Divilio.	Di:11:9
THE WITNESS: No. 11 Q. Divilio? Who's Dr. Thomas	
12 BY MR. THORNBURGH: 12 A. He was a medical director at	Etnicon.
Q. How could you do a degradation study 13 It doesn't look like I sent the	:,
14 without doing SEM analysis? 14 message. It looks like I was copied on the state of the state	
MR. THOMAS: Object to the form of 15 MR. THOMAS: He directed to the form of 16 MR. THOMAS: He directed to the form of 15 MR. THOMAS:	your
16 the question. 16 attention to the very end.	
THE WITNESS: Well, the beauty the 17 Oh, I see. Yes, I see what you	
18 beauty of an implantation study is that you can look 18 THE WITNESS: I am looking	
19 at the elements of an implant to determine whether 19 last e-mail message beginning on ETH.	MESH.05588125.
20 or not there is cracking, there's absorption, there 20 BY MR. THORNBURGH:	41
21 is surface effects. All that could be visualized 21 Q. Yeah. Oddly, if you look at the could be visualized 21 and the could be visualized 22 and the cou	
22 directly under the light microscope. 22 author of this e-mail, it appears to be you	ou.
23 BY MR. THORNBURGH: 23 Hold on a second.	4-
Q. In fact, you were told not to do 24 MR. THOMAS: Wait a minute of the second strength of	
25 degradation studies, weren't you? 25 MR. THORNBURGH: I'm so	······································

20 (Pages 367 to 370)

Page 371 Page 373 Strike that. Strike that. 1 after ten years revealed no changes in material. 2 2 MR. THOMAS: The author is Tom That's not actually true, is it? 3 3 MR. THOMAS: Object to the form of Divilio. 4 MR. THORNBURGH: That's why I said 4 the question; scope. 5 "strike that". 5 BY MR. THORNBURGH: 6 6 That statement that Ethicon had BY MR. THORNBURGH: Q. 7 7 O. Well, let's do it this way. Do you previously implanted Prolene suture into dogs, and 8 recall being included in an e-mail, copied in an 8 explants after ten years revealed no changes in the 9 9 e-mail, from Dr. Thomas Divilio to John Gillespie material, is not a true statement, is it? where you were copied --10 MR. THOMAS: Object to form; scope. 10 11 THE WITNESS: There were three MR. THOMAS: Object to form. 11 12 BY MR. THORNBURGH: 12 elements, three important elements in that study. 13 13 Q. -- as a recipient of the e-mail? The key elements, as we've discussed MR. THOMAS: Object to the form of 14 14 earlier, were molecular weight and tensile strength. 15 the question; scope. 15 And in that seven-year dog study, which -- which is 16 THE WITNESS: Well, I've never seen 16 referenced as ten year here, there was no impact on 17 this e-mail chain before. I'd like to take a minute molecular weight, nor tensile strength. 18 18 to go -- to read through it. BY MR. THORNBURGH: 19 BY MR. THORNBURGH: 19 Q. There was surface cracks observed on 20 Well, you clearly received it. You 20 the surface layer of the polypropylene in that don't recall it. Is that what you're saying? 21 21 study, correct? 22 22 MR. THOMAS: Object to the form of A. Surface changes were observed in some 2.3 of the fibers in some of the dogs. 23 the question. 24 THE WITNESS: I see that I'm copied 24 Are you telling the ladies and 25 on it. You asked me if I knew anything about it. gentlemen of the jury that when the outer surface of Page 372 BY MR. THORNBURGH: the polypropylene fibers crack and peel away from 2 We'll read the e-mail. 2 the surface, that that is not degradation? 3 It says from Dr. Divilio, John --3 MR. THOMAS: Object to the form of 4 MR. THOMAS: I think he wants to read 4 the question. 5 the whole chain. 5 THE WITNESS: I am telling listeners 6 MR. THORNBURGH: Okay. I mean, I am б that the key endpoint of adverse effects of 7 going to read it with him. 7 degradation are molecular weight and tensile 8 THE WITNESS: Okay. If you want to 8 strength, both quantitative measures, not subjective lead it off, that's fine. 9 assessments of surface changes, but quantitative BY MR. THORNBURGH: measures that hold great weight and suggest that 10 10 It says: John, Bruce Ramshaw from 11 11 there's no degradation to the Prolene fiber in terms the University of Missouri is challenging our 12 that are significant. 12 13 perception of polypropylene --13 BY MR. THORNBURGH: Polypropylene is the polymer in TVT, 14 14 Do you agree there's been studies 15 15 conducted that show that when the polypropylene correct? 16 Yes. fiber surface or lose -- or fragments come off of A. 17 -- is challenging our perception of 17 the polypropylene surface as a result of Q. 18 polypropylene as inert material after implantation. 18 degradation, that that increases the inflammatory In a recent article, his group looked at explanted 19 19 response? polypropylene from a Bard Composix mesh under EM and 20 MR. THOMAS: Object to the form of found that the surface of the fibers had been 21 21 the question. altered with respect to the pristine material, with 22 22 BY MR. THORNBURGH: evidence of blistering and increased surface 23 Q. You've seen those studies, haven't 24 roughness, possibly due to oxidation. We previously 24 you? had implanted Prolene suture into dogs, and explants 25 MR. THOMAS: Object to the form of

21 (Pages 371 to 374)

	Page 375		Page 377
1	the question.	1	in TVT does not degrade as a result of tissue
2	THE WITNESS: I don't recall those	2	enzymes is a study conducted by Postlethwait, right?
3	studies. However, all of those studies I do	3	You recall this study, don't you?
4	recall and it's those 49 studies listed in these	4	MR. THOMAS: Which one are we talking
5	two folders do not suggest that there's	5	about?
6	degradation of the Prolene polypropylene fiber.	6	BY MR. THORNBURGH:
7	BY MR. THORNBURGH:	7	Q. Long-term comparative study of
8	Q. Do you agree on behalf of Ethicon	8	non-absorbable sutures by Dr. Postlethwait from 1969.
9	that if that that if the surface layer is coming	9	ETH.MESH. Number 10575759.
10	off and/or there are fragments that are being	10	MR. THOMAS: Excuse me. Do you want
11	released from the polypropylene, that that would	11	to mark one of those for the record?
12	could increase increase the inflammatory	12	MR. THORNBURGH: Yes. Yes, I do.
13	response?	13	THE WITNESS: Did you say 59?
14	A. No.	14	MR. THOMAS: Wait a minute. He's
15	MR. THOMAS: Object to the form of	15	going to mark it for you.
16	the question.	16	MR. THORNBURGH: I am going to give
17	THE WITNESS: No, because every bit	17	you a copy so you have it.
18	of data that Ethicon has and there are 49 studies	18	THE WITNESS: I have a copy here.
19	listed here suggest that if anything, the tissue	19	It's Tab
20	reaction after long-term implantation of Prolene	20	MR. THORNBURGH: I am going to mark
21	polypropylene fibers diminishes. It does not	21	this one, anyway.
22	increase.	22	I'm sorry, Dave.
23	And this is reflected by FDA in the	23	MR. THOMAS: Can I have one, please?
24	FDA reclassification document, where they discuss	24	MR. THORNBURGH: Yep.
25	what's known about Prolene suture and that, in fact,	25	MR. THOMAS: What exhibit number is
	Page 376		Page 378
1	that it's not absorbable and doesn't degrade to a	1	that?
2	significant effect.	2	THE WITNESS: 2251.
3	MR. THORNBURGH: Move to strike.	3	MR. THOMAS: 2251. Thank you.
4	BY MR. THORNBURGH:	4	(Document marked for identification
5	Q. It's a yes or no question, and then	5	as Exhibit T-2251.)
6 7	you can explain it if you want to.	6 7	BY MR. THORNBURGH:
8	My question to you was: Is it	8	Q. Now, Dr. Postlethwait from Duke
9	Ethicon's position MR. THOMAS: Excuse me. Just so you	9	University Medical Center in 1969, in a study supported by Ethicon, looked at degradation of
10	know, he said "no" and then explained. That's	10	polypropylene fibers or sutures.
11	exactly what he did.	11	And if you turn to Page 895, and if
12	MR. THORNBURGH: All right. Move to	12	you go to the first figure six at the bottom, it
13	strike everything after no.	13	shows that M this is a hard copy to read, but in
14	It's going to be a long day if	14	Picture M or Image M, polypropylene apparently,
15	counsel	15	Image M is showing polypropylene with some fragments
16	BY MR. THORNBURGH:	16	after 18 months.
17	Q. Counsel, obviously, is going to have	17	Same at two years. Higher power of
18	an opportunity to ask you questions. But I asked a	18	edges of polypropylene suture and fragments.
19	yes or no question. I expect a yes or no answer.	19	Now, if we turn to ETH.MESH.0175763,
20	MR. THOMAS: He knows the rules, Dan.	20	the last full paragraph on the left-hand column
21	This is his sixth day.	21	discusses Dr. Postlethwait's findings with respect to
22	BY MR. THORNBURGH:	22	the polypropylene sutures which were apparently
23	Q. Doctor, in fact, one of the pieces of	23	provided to him by Ethicon.
24	evidence that you included in your list of documents	24	MR. THOMAS: Whoa, whoa, whoa.
25	related to the statement by Ethicon that the Prolene	25	Object to the form of the question. Where can you

22 (Pages 375 to 378)

Page 379 Page 381 substantiate that? 1 MR. THOMAS: He already has. 1 2 MR. THORNBURGH: Well, it's provided BY MR. THORNBURGH: 3 3 Now, if we go back to Exhibit in part by Ethicon. 4 MR. THOMAS: Nowhere in this article 4 Number 4012: Bruce, the e-mail from Dr. Divilio to 5 does it say these are Ethicon sutures, unless you 5 John Gillespie. 6 6 can show me otherwise. Who's John Gillespie? 7 7 MR. THORNBURGH: Are you representing A. He worked in the Gynecare group, 8 that they're not? 8 so... 9 9 MR. THOMAS: I am not, but I think Q. And you were cc'd, weren't you? it's another thing to say that they were. 10 10 A. Yes. BY MR. THORNBURGH: 11 11 And the subject of this e-mail is how O. 12 12 inert is polypropylene, right? Q. Well, certainly, Ethicon is 13 13 supporting this study, right? A. Yes. 14 14 And this study is regarding Q. Okay. Now, Dr. Divilio writes to 15 polypropylene degradation. And Dr. Postlethwait 15 John: Bruce Ramshaw from the University of Missouri writes that in 18 months and more -- at 18 months, 16 is challenging our perception of polypropylene as an 17 and even more often at two years, an occasional inert material after implantation. suture has started to fragment. The entire suture 18 18 Do you recall other experts in the 19 does not break up, but small portions appear to 19 field who have evaluated and studied the 20 separate from one edge. potentiation of polypropylene degradation having a 21 Each minute fragment, although different position than Ethicon has currently in 22 22 remaining in the vicinity, stimulates its own this litigation? 23 cellular reaction. This, of course, increases the 2.3 MR. THOMAS: Object to the form of grade of the tissue reaction so that it exceeds 24 the question. 25 nylon. 25 THE WITNESS: Yeah. You'll have Page 380 Page 382 So Dr. Postlethwait, who personally to -- are we talking about this memo, or is it a studied this issue with polypropylene, found that standalone question? 3 fragments, no matter how minute, increases the grade 3 BY MR. THORNBURGH: 4 of tissue reaction. 4 Standalone question first. Q. 5 5 Do you disagree with Dr. And that would be? A. 6 Experts in the field who study б Postlethwait's statement here? Q. 7 7 MR. THOMAS: Object to the form of degradation of polypropylene have a different 8 the question. 8 position than Ethicon is taking through you in this 9 THE WITNESS: He says: This, of 9 litigation, correct? 10 10 course, increases the grade of the tissue reaction MR. THOMAS: Object to the form of so that it exceeds nylon. 11 11 the question. 12 BY MR. THORNBURGH: 12 THE WITNESS: The position that 13 It increases the tissue reaction, 13 Ethicon is taking, there's no impact on molecular Q. 14 correct? weight or tensile strength. I don't know of other MR. THOMAS: Object to the form of 15 investigators that demonstrate with Prolene 15 polypropylene fiber a loss of molecular weight and 16 the question. THE WITNESS: To exceed nylon, which 17 loss in tensile strength. 17 18 I know has virtually little reaction. 18 BY MR. THORNBURGH: 19 19 BY MR. THORNBURGH: Are you saying Ethicon that is not 20 Q. It increases the tissue reaction, 20 taking the position that the surface layer of the 21 correct? 21 polypropylene fibers does, in fact, crack and can 22 A. 22 peel away from the surface of the fibers? Yes. 23 O. You would agree with that statement, 23 MR. THOMAS: Object to the form of 24 wouldn't you? 24 the question. 25 Yes. 25 THE WITNESS: We can look at the

23 (Pages 379 to 382)

Page 383 Page 385 details of the seven-year dog study which do show question. 2 BY MR. THORNBURGH: surface changes in some of the fibers from some of 3 3 the dogs. Do you agree as a spokesperson for 4 4 MR. THOMAS: Excuse me --Ethicon that the polymer fibers can crack? 5 5 MR. THOMAS: Object to the form of THE WITNESS: In the absence --6 MR. THORNBURGH: I thought he was 6 the question. 7 7 done, Dave. THE WITNESS: I think I just answered 8 THE WITNESS: In the absence of 8 that --9 9 impact of molecular weight or tensile strength. BY MR. THORNBURGH: 10 BY MR. THORNBURGH: 10 Yes or no? Q. 11 11 Right. But you agree Ethicon -- as a I think I just answered that those 12 spokesperson for Ethicon, that the surface of the 12 observations are in the seven-year dog study. So we 13 13 polymer fibers can, in fact, crack and peel away can look at those details if you care to. 14 So you would agree as a 14 into the surrounding tissue of either the patient or 15 an animal? 15 spokesperson -- as a 30(b)(6) person for Ethicon 16 16 that the surface of polymer fibers, including the MR. THOMAS: Object to the form of 17 polypropylene fibers in TVT, can crack? the question. 18 18 THE WITNESS: I recall observations MR. THOMAS: Object to the form of 19 of surface cracking in the seven-year dog study, but 19 the question. 20 I don't recall any discussion of surface peeling 20 THE WITNESS: Yes. 21 21 away and -- to your -- to your detail. BY MR. THORNBURGH: 22 BY MR. THORNBURGH: And you would agree that if fragments 22 23 Well, we'll look -- we'll look at 23 come off of the polypropylene fibers, including the 24 some other studies here in a moment. But let me at polypropylene fibers in TVT, that that could least understand Ethicon's position with respect to increase or that could cause each minute fragment to Page 384 Page 386 surface cracking. stimulate its own cellular reaction. You would 1 2 2 Is it Ethicon's position that the agree with that, right? 3 polymer fiber surface can, in fact, crack? 3 MR. THOMAS: Object to the form of 4 MR. THOMAS: Object to the form of 4 the question. 5 5 THE WITNESS: No. There's no the question. б THE WITNESS: Such observations were б evidence that there's -- in the seven-year dog study 7 made in the seven-year dog study. 7 that material that is coming from the surface other 8 BY MR. THORNBURGH: 8 than showing surface changes in the form of -- of 9 So it's Ethicon's position that the 9 cracking. 10 10 polymer fibers can crack, right? I should add that in the Prolene 11 MR. THOMAS: Object to the form of 11 suture NDA, observations of polypropylene fragments 12 the question. were observed and reported to the FDA. And they 13 THE WITNESS: Again, the seven-year were felt to be related to this swaging process or 14 dog study talks about surface changes. The etiology the cutting of suture strands to length, and a of those changes or their significance are not 15 fragment would be attached to the suture and get 15 discussed in detail other than to follow up on that 16 inadvertently implanted. 16 17 observation and look at more important quantitative I should also point out in the 17 18 parameters, like molecular weight and tensile 18 Postlethwait study that we just discussed, 19 19 strength, and those two parameters were not Exhibit 2251, ETH.MESH.10575764, at the top of the 20 adversely affected. 20 page, right after the discussion section where it 21 BY MR. THORNBURGH: 21 says that there are fragments which increase the 22 I know you want to try to frame the 22 tissue reaction -- at the top of the page, it says: position most favorable to Ethicon, but listen to my 23 In correspondence with the manufacturer, it was learned that these sutures were 24 question. Okay? 24 the first extruded from the first shipment of 25 MR. THOMAS: Please don't load the

24 (Pages 383 to 386)

Page 387 Page 389 polypropylene. Subsequently, changes have been made products. to improve the extrusion process. It is believed 2 Don't you think surgeons should know that fragmentation will not occur with the presently 3 that the -- that the surface layer of the TVT mesh, available sutures. Additional long-term studies 4 a device that's being implanted permanently in 5 have been initiated, however. 5 women's pelvises -- don't you think they should know 6 And then, parenthetically, the and be made aware that, in fact, the tissue enzymes 7 7 can cause the surface layer of the TVT to crack? polypropylene did retain tensile strength. 8 BY MR. THORNBURGH: 8 MR. THOMAS: Object to the form of 9 9 It still increased the inflammatory the question; scope. 10 response, didn't they? 10 THE WITNESS: To the first part of 11 your question, no, I don't think they care...if, 11 MR. THOMAS: Object to the form of 12 12 there's no impact on molecular weight and there's no the question. THE WITNESS: An individual fragment 13 13 increase -- there's no decrease in tensile strength. 14 And all the tissue reaction studies show a very 14 adjacent to a strand of polypropylene -- Prolene 15 polypropylene fiber will add to the inflammatory 15 minimal tissue reaction and, in fact, a diminution 16 reaction just like there is an inflammatory reaction of that reaction over time. 16 17 to the suture fiber itself. 17 BY MR. THORNBURGH: That's wholly different than what 18 18 You don't think physicians should be 19 you're talking about when you suggest that there's 19 made aware of the potential of degradation of the --20 surface cracking and sloughing of the surface, 20 or surface cracking of the polymer fibers that's 21 releasing many particles. 21 being used as a permanent implant in women's 22 22 If that's the case, that observation pelvises? That's what you're telling the ladies and 23 23 would have been observed -- that observation of gentlemen of this jury? increased tissue reaction would have been observed 24 MR. THOMAS: Excuse me. Object to 25 in the 49 studies that we've compiled to demonstrate 25 the form of the question; scope. Page 388 Page 390 1 that, in fact, that that does not occur; and, in THE WITNESS: Could you repeat the 2 fact, there's a diminution of the tissue reaction question? BY MR. THORNBURGH: 3 over time in many cases from Ethicon's data and as 3 called out by FDA in the reclassification. 4 Yeah. Let me say it this way. 5 5 MR. THORNBURGH: Move to strike. Ethicon chose not to include BY MR. THORNBURGH: б information in this section from animal studies that б 7 7 We're going to be here a long day if showed that the -- that the Prolene and you keep on going on this platform and speaking when 8 8 polypropylene surface area can crack, right? 9 there's not even a question pending. 9 MR. THOMAS: Object to the form of MR. THOMAS: Please don't lecture the 10 10 the question. witness. 11 THE WITNESS: I believe that Ethicon 11 MR. THORNBURGH: Move to strike. 12 did not feel that that was important information to 12 13 MR. THOMAS: Please don't lecture the 13 put in the instructions for use. BY MR. THORNBURGH: 14 witness. 14 15 BY MR. THORNBURGH: 15 And because that information wasn't Dr. Barbolt, where in this section in put into the -- and because Ethicon chose not to put 16 Q. the IFU that talks about degradation does Ethicon 17 that information in the IFU, that information, 17 18 warn physicians that the surface layer of the 18 therefore, did not make it to the physicians? 19 MR. THOMAS: Object to the form of 19 Prolene in the TVT mesh can crack? 20 MR. THOMAS: Object to the form of 20 the question; scope. BY MR. THORNBURGH: the question; scope. 21 BY MR. THORNBURGH: 22 Q. Correct? 22 23 O. It's not in there, is it? 23 A. That level of detail was not provided This is an IFU intended to provide 24 in the package insert. 24 A. 25 25 the most useful information to surgeons who use our MR. THORNBURGH: I have to use the

25 (Pages 387 to 390)

Page 391 Page 393 the question; scope. 1 restroom. 2 2 THE VIDEOGRAPHER: Off the video THE WITNESS: I don't think oxidation 3 3 record. The time is 11:18. was an issue that needed to be corrected. 4 (Short break.) 4 BY MR. THORNBURGH: 5 THE VIDEOGRAPHER: Back on the video 5 Well, surface cracking was, right? O. 6 6 record. It's 11:24. MR. THOMAS: Object to the form of 7 7 BY MR. THORNBURGH: the question. 8 Now, Doctor, you made a statement a 8 THE WITNESS: What we were discussing 9 9 moment ago regarding the Postlethwait publication before was fragmentation, and I see that as totally study, that changes were made by the manufacturers different than observations of surface cracking. 10 subsequent to this study, correct? 11 BY MR. THORNBURGH: 11 12 12 A. Yes, as I read from the publication. Q. Okay. 13 13 Q. And this study was 1969, right? A. Fragmentation is a growth fragment of Yes. A Prolene suture was just being the suture. Surface cracking is a very subtle 14 A. 14 15 released as a new product. 15 observation of what looks like surface cracking. 16 Okay. Now --16 You agree with me that by 1985, Q. MR. THORNBURGH: I'll go ahead and 17 17 Ethicon would have added antioxidants, like Santonox R and Procol or Lubrol, to their resin 18 mark as exhibit -- Exhibit Number 2252... 18 19 (Document marked for identification 19 during the manufacturing process to prevent 20 as Exhibit T-2252.) 20 oxidation, right? 21 21 MR. THORNBURGH: ... the five-year Antioxidant package was added at the 22 very beginning of the development of the Prolene data from the ten-year dog study. 23 Mr. Thomas. 2.3 suture and has remained basically unchanged. 24 MR. THOMAS: Can I have a copy, 24 And as we discussed earlier, you 25 please? agree that the antioxidants, including Santonox R Page 392 Page 394 MR. THORNBURGH: Yes. and Lubrol and Procol, can leach out of the mesh or 2 BY MR. THORNBURGH: suture fibers into the surrounding tissue of the 3 I'm sorry. Hold on. Yeah. 3 host, right? 4 Okay. Now, this document is the --4 MR. THOMAS: Object to the form of is the five-year data from the ten-year dog study 5 5 the question. that we've been alluding to all along, right? б THE WITNESS: Yes. I think there's 6 7 7 evidence of leaching. Α. Yes. 8 Q. And this is the study that you 8 BY MR. THORNBURGH: testified showed cracks in the surface layer, outer 9 All right. And in this study, surface layer, of the polypropylene sutures, 10 despite the antioxidants being added to the Prolene 10 sutures, the surface layer or outer surface of the correct? 11 11 MR. THOMAS: Object to the form of 12 polypropylene fibers cracked, correct? 12 13 MR. THOMAS: Object to the form of 13 the question. 14 THE WITNESS: As indicated in the 14 the question. 15 15 THE WITNESS: I want to look at the reports, right. BY MR. THORNBURGH: details of the report and... 16 17 BY MR. THORNBURGH: 17 Q. And this study was -- began in 1985. 18 Do you see that? 18 Q. Did you see this before today? 19 19 A. Yes. Yes. Α. 20 Okay. That -- that's like 16 years 20 Q. Okay. after the Postlethwait publication. And presumably 21 I've not memorized every paragraph. A. by this point, the manufacturers, including Ethicon, 22 Let's go through it together. 22 23 had made the necessary changes to their Prolene 23 MR. THOMAS: Well, wait. There was a 24 suture to prevent oxidation, right? question pending. Do you want to withdraw it and 24 25 MR. THOMAS: Object to the form of ask another?

26 (Pages 391 to 394)

Page 395 Page 397 BY MR. THORNBURGH: and discussion section, on Page 2 of Exhibit 1 2 I think the question was... Number 2252, which is the five-year data, the 3 MR. THOMAS: Your question at 91, 11. investigator and author of this report writes that: 4 BY MR. THORNBURGH: A table is included in this report which summarizes 5 5 the light microscopical observations. It can be In this study, despite the antioxidants being added to the Prolene sutures, the 6 said unequivocally that the cracking that was seen 7 7 surface there or outer surface of the polypropylene in any of the sutures was not introduced by sample 8 fibers cracked, correct? 8 preparation, i.e., drying. 9 9 MR. THOMAS: He never answered that If cracking was observed on a dry 10 10 suture in the light microscope or in the SEM -question. 11 11 THE WITNESS: Yes, and I want to take scanning electron microscopy -- the same cracking is 12 a look at the report so I can recall just what was 12 also found on the same suture after it had been in 13 13 written, because I am trying to reflect the report. body fluids and then in sterile water without ever BY MR. THORNBURGH: 14 14 having dried. 15 Well, we can go through it together 15 So this reporter, the researcher at Q. to help you answer that question. 16 16 Ethicon, wrote that it can be said unequivocally 17 I am looking at the bottom of that the cracks were not caused by the introduction ETH.MESH.11336475, and looking at the conclusions, 18 18 by sample preparation, right? 19 and then it says out of seven Prolene explants, two 19 A. Yes. That's what it says. 20 revealed cracking. 20 And if we go to -- on the same page, Q. 21 So the answer to my question is yes. 21 if we go to the third section regarding SEM, Q. 22 MR. THOMAS: Object to the form of scanning electronic microscopy, of PVDF explants, it 23 was found that no cracking or abrasions were found 23 the question. 24 THE WITNESS: This is a complete on the PVDF sutures, correct? 25 25 Yes. At this interval, that's answer. Page 396 Page 398 BY MR. THORNBURGH: correct. 2 2 Despite the antioxidants being added Q. But at this five-year interval, the 3 to the Prolene sutures, in two of the Prolene scanning electron microscopy of Prolene explants on sutures in the study, the surface layer was cracked, explants from dogs 2012 and 2018, a few cracked 5 areas were observed. Both of these sutures came correct? б from Site 4. Do you see that? б MR. THOMAS: Object to the form of 7 7 Α. the question. Yes. 8 THE WITNESS: Two revealed cracking, 8 Q. And the conclusion that we discussed 9 9 a moment ago was that after five years in vivo, the yes. BY MR. THORNBURGH: PVDF -- do you know what PVDF is? 10 10 11 And you aren't suggesting to the 11 A. Yes. ladies and gentlemen of the jury that those cracks 12 That's a more stable, more inert were anything other than the Prolene polypropylene, 13 fiber, isn't it? 13 14 are you? 14 MR. THOMAS: Object to the form of 15 A. No, I am not suggesting that, and 15 the question. that's not reflected in this report. BY MR. THORNBURGH: 16 16 You would agree that the surface 17 17 It's a polymer? 18 layer that's cracked here is the polypropylene 18 MR. THOMAS: Object to the form of 19 surface layer, correct? 19 the question; scope. 20 MR. THOMAS: Object to the form of 20 THE WITNESS: It is a very resistant 21 21 the question. to degradation kind of polymer and resistant to THE WITNESS: In reading the report, 22 mechanical damage. 22 23 it says that -- that's what I would conclude. 23 BY MR. THORNBURGH: BY MR. THORNBURGH: 24 24 More so than Prolene, correct? 25 25 And if we look back up at the results MR. THOMAS: Object to the form of

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Page 399 Page 401 THE WITNESS: None shown. the question; scope. 1 1 2 THE WITNESS: Yes. BY MR. THORNBURGH: 3 BY MR. THORNBURGH: Which would be consistent with your 4 And the conclusion was that after testimony that the PVDF polymer is a more inert 5 five years in vivo, the PVDF 5-0 suture was the only 5 polymer than Prolene polypropylene? 6 explanted material from the five dogs which did not 6 MR. THOMAS: Object to the form of 7 7 show any surface damage due to degradation. Out of the question; scope. 8 seven Prolene explants, two revealed cracking. 8 BY MR. THORNBURGH: 9 9 So in this study, at the five year --Q. Right? the two-year data in this study didn't show evidence 10 A. Yes. 10 of cracking, but the five-year data, the long-term 11 11 O. Finally, if we go to the conclusion data, showed evidence of cracking of the Prolene 12 page on the five-year data, ETH.MESH.11336487, the 12 sutures, correct? conclusion here is that after five years in vivo, 13 the PVDF 5-0 suture was the only explanted material 14 A. Yes. That's what it says. 15 Q. And here is the table that was 15 from five dogs which did not show any surface damage due to degradation. referenced by the study investigator which shows 16 16 cracking on the Prolene fibers. Do you see that? 17 17 So here the study author is 18 discussing degradation, right? 18 A. Yes. 19 Q. Finally, on ETH.MESH. number ending 19 MR. THOMAS: Object to the form of 20 in 6483, there are -- there is SEM images, though 20 the question. 21 they're black and white, they show the cracking that 21 THE WITNESS: Yes. It's as stated. 22 BY MR. THORNBURGH: 22 was observed in the five-year data. Do you see 23 2.3 And included in his analysis of that? 24 MR. THOMAS: What page are you on? 24 degradation is his observation that the Prolene 25 explants did show signs of degradation as a result I'm sorry. Page 400 Page 402 MR. THORNBURGH: ETH.MESH.6483. of the surface cracking on the outer layer of the 2 2 BY MR. THORNBURGH: polymer, correct? 3 Q. This is an upside down page, for some 3 A. As reported. 4 reason, but --4 Q. Correct? Yes? 5 5 Yes. A. Yes. I see it. A. 6 б -- if you see Figure 6, Prolene Q. Now, this study and the findings in Q. 7 7 explants, you can see the cracking, even in this the study showing that the polypropylene can crack poor copy image, of the Prolene polypropylene that 8 on the surface of the Prolene sutures was conducted 9 was cracked on the surface of the sutures, right? 9 nine -- approximately nine -- eight or nine years MR. THOMAS: Object to the form of prior to the marketing of TVT, correct? 10 10 11 Yes. August 10, 1990 is the date of 11 the question. A. THE WITNESS: Yes. I see that. 12 12 the report. 13 BY MR. THORNBURGH: 13 Q. And prior to Ethicon's claim in the 14 Figure 4, ETH.MESH.6481, we have the 1999 label that the material is not absorbed, nor is 15 PVDF explants, which you testified was a more inert 15 it subject to degradation or weakening by the action polymer than polypropylene and Prolene 16 of tissue enzymes, correct? 16 polypropylene, which shows, really, fibers that look 17 One cannot look at this -- this 17 A. 18 almost pristine, right? 18 observation. 19 19 MR. THOMAS: Object to the form of Q. Yes or no, sir. 20 20 I can't give a "yes" or "no" answer. the question. A. 21 THE WITNESS: Yes. It's a really easy question. 21 Q. 22 BY MR. THORNBURGH: 22 No, it's not. A. 23 O. No crack, no surface cracking on the 23 Q. The study -- the 1990 study was 24 PVDF? conducted nine years before the 1990 label which 24 25 MR. THOMAS: Same objection. included the claim that the material is not

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Page 403 Page 405 absorbed, nor is it subject to degradation or is not absorbed, nor is it subject to degradation or weakening by action of tissue enzymes, correct? weakening by action of tissue enzymes. Correct? 3 3 MR. THOMAS: He's just asking you now A. Yes. 4 about the date, Tom, nothing more. 4 Q. And additional studies were performed 5 THE WITNESS: The date is August 10, 5 on the Prolene sutures at this seven-year interval, 1990. 6 correct? 7 7 BY MR. THORNBURGH: For example, IR microscopy was used 8 Nine years prior to this claim in the 8 to examine cracked areas in Ethilon, Novofil, and 9 9 IFU, correct? Prolene explants. And the conclusion written here 10 MR. THOMAS: Object to the form of 10 or the findings summarized here is that the IR 11 11 the question. spectra obtained for cracked Prolene specimens, 12 12 Figure A, showed possible evidence of slight THE WITNESS: Yes. 13 13 MR. THORNBURGH: Let's go ahead and oxidation with a broadened weak absorbance at about the 1560 range. Do you see that? 14 mark the seven-year data. 14 15 (Document marked for identification 15 MR. THOMAS: 1650 range. as Exhibit T-2253.) 16 BY MR. THORNBURGH: 16 17 Yeah, 1650 range. 17 BY MR. THORNBURGH: I marked the seven-year data 18 18 A. Yes. 19 ETH.MESH.11336034 as Exhibit 2253. 19 Q. You see that, right? 20 20 Doctor, you've had an opportunity A. Yes. 21 prior to coming into this room for your deposition 21 Q. So not only were -- did the sutures 22 to review the seven-year data for the ten-year show evidence of surface cracking, but the IR 23 spectra also showed that there was evidence of 23 Prolene dog study, correct? 24 A. Yes. oxidation? 25 25 MR. THOMAS: Object to the form of Q. And the seven-year data --Page 404 Page 406 1 MR. THOMAS: Just -the question. MR. THORNBURGH: Sorry? 2 2 Read the complete sentence, please. 3 MR. THOMAS: There's additional data 3 MR. THORNBURGH: Dave, you'll have a reported at seven years. This is not the totality chance to make representations. I am showing the 5 of the data. I wanted to make sure that you weren't 5 jury IR spectra obtained for cracked Prolene representing that to be the totality of the data. б б specimen showed possible evidence of slight 7 MR. THORNBURGH: Well, that's -- in 7 oxidation. 8 8 the report. This is the report. MR. THOMAS: That is a proper 9 MR. THOMAS: It's not the totality of 9 reading --10 10 the data. There's seven-year data that's also been MR. THORNBURGH: Move to strike produced to you. your -- move to strike your -- Dave, if you're going 11 11 12 MR. THORNBURGH: Well, I understand to try to make these speaking objections and that. I understand that. We're going to talk about 13 suggesting answers to the witness, then I am going 13 14 this report currently, and if there's a need to, 14 to call the Judge. I'll go to the other -- the other additional data. 15 15 MR. THOMAS: You call the Judge --I don't know that there's a need to do that, but 16 MR. THORNBURGH: Okay? 16 we'll get there, Dave. Don't worry. 17 17 MR. THOMAS: -- because you are 18 And if I don't cover something that 18 representing this to be something else. you think is important, Dave, you'll have a chance 19 MR. THORNBURGH: Because speaking 19 20 to make those representations to the jury during 20 objections -- because speaking objections are your cross-examination or direct examination. 21 inappropriate. The question remains especially when 22 BY MR. THORNBURGH: 22 they suggest answers -- okay? 23 O. Dr. Barbolt, October 15, 1992, that 23 MR. THOMAS: I certainly know the rules, Dan. I certainly know the rules. Thank you. again is several years prior to the claim that was 24 Let's move on. made in the IFU that we looked at that the material

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1	Page 407		Page 409
	BY MR. THORNBURGH:	1	BY MR. THORNBURGH:
2	Q. IR spectra showed possible evidence	2	Q. And that's Ethicon's position as
3	of slight oxidation, correct?	3	you as the spokesperson for Ethicon, it's
4	A. Yes.	4	Ethicon's position that degradation, surface
5	Q. Okay. Now, there's also an	5	degradation, can occur, correct?
6	observation regarding the other Ethilon and Novofil,	6	MR. THOMAS: Object to the form of
7	which differed from uncracked areas. And the	7	the question.
8	conclusion was, expected IR absorbances for	8	THE WITNESS: Yes.
9	oxidation would be masked by strong carbonyl	9	BY MR. THORNBURGH:
10		10	
	absorbances normally observed in these sutures.		Q. And this was known well in advance of
11	So there's a discussion here that	11	this statement that the material is not absorbed,
12	of the what would be expected to be seen could be	12	nor is it subject to degradation, correct?
13	masked by strong carbonyl absorbances. Do you see	13	A. Yes. This is from 1992.
14	that?	14	MR. THORNBURGH: Okay. Lunch break.
15	MR. THOMAS: Object to the form of	15	THE VIDEOGRAPHER: We're now going
16	the question.	16	off the video record. It's 11:48.
17	THE WITNESS: Yes.	17	(Lunch break.)
18	BY MR. THORNBURGH:	18	THE VIDEOGRAPHER: We're back on the
19	Q. And at the seven-year data, Ethicon's	19	video record. It's now 12:43.
20	investigator found degradation in Prolene is still	20	BY MR. THORNBURGH:
21	increasing in PVDF even though a few cracks were	21	Q. Now, Doctor, I'd like to turn your
22	found, is still by far the most surface resistant	22	attention back to the e-mail that we began to
23	in-house made suture in terms of cracking.	23	discuss earlier in your deposition, Exhibit
24	That's the findings by Ethicon's	24	Number T 4012.
25	investigator, right?	25	(Whereupon, a discussion was held off
	Page 408		Page 410
1	A. Yes.	1	the record.)
2	Q. An employee for Ethicon who actually	2	THE WITNESS: Okay.
3	investigated degradation of Prolene sutures and came	3	BY MR. THORNBURGH:
4	to the conclusion that degradation is occurring in	4	Q. Now, this e-mail
_	Prolene, right?		
5		5	MR. THOMAS: Give me just a half a
5 6		5 6	y .
	MR. THOMAS: Object to the form of		second to get back on the same page.
6	MR. THOMAS: Object to the form of the question.	6	second to get back on the same page. Thank you. I am ready.
6 7 8	MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH:	6 7 8	second to get back on the same page. Thank you. I am ready. BY MR. THORNBURGH:
6 7 8 9	MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Do you see that?	6 7	second to get back on the same page. Thank you. I am ready. BY MR. THORNBURGH: Q. This e-mail is again from
6 7 8 9 10	MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Do you see that? A. Yes, I see that. Surface	6 7 8 9	second to get back on the same page. Thank you. I am ready. BY MR. THORNBURGH: Q. This e-mail is again from Dr. Divilio, and you were copied on this e-mail,
6 7 8 9 10 11	MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Do you see that? A. Yes, I see that. Surface degradation, and they're making a reference to	6 7 8 9 10 11	second to get back on the same page. Thank you. I am ready. BY MR. THORNBURGH: Q. This e-mail is again from Dr. Divilio, and you were copied on this e-mail, right?
6 7 8 9 10 11 12	MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Do you see that? A. Yes, I see that. Surface degradation, and they're making a reference to surface degradation. Yep. I see it.	6 7 8 9 10 11 12	second to get back on the same page. Thank you. I am ready. BY MR. THORNBURGH: Q. This e-mail is again from Dr. Divilio, and you were copied on this e-mail, right? A. Yes.
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Page 411 Page 413 similar findings, at the very least, that were made no changes were in molecular weight and tensile in the five-year and seven-year, ten-year dog study, strength. So they might have been in this memo 3 making reference to the more important quantitative correct? 4 MR. THOMAS: Object to the form of parameters like molecular weight and tensile 5 5 the question. strength. 6 BY MR. THORNBURGH: THE WITNESS: No. In that study, 7 7 there was descriptions like surface cracking. I Well, Dan Burkley found in the 8 don't see that here. 8 seven-year data that there was degradation in the 9 9 BY MR. THORNBURGH: Prolene, right? 10 Well, it says: The surface of the 10 MR. THOMAS: Object to the form of 11 11 fibers had been altered with respect to the pristine the question. 12 12 material. THE WITNESS: That's in the report. That could include and would include 13 13 That's an observation. That's a component of the 14 surface cracking, wouldn't it? 14 parameters investigated in this study. 15 MR. THOMAS: Object to the form of 15 BY MR. THORNBURGH: 16 The statement made by Dr. Divilio 16 the question. 17 THE WITNESS: As I read forward, it 17 that we had previously implanted Prolene suture into 18 says -- and they define what they mean by alteration 18 dogs, and explants after ten years revealed no 19 by saying evidence of blistering and increased 19 changes in the material, is not a completely true 20 surface roughness, possibly due to oxidation. 20 statement, is it? 21 21 BY MR. THORNBURGH: MR. THOMAS: Object to the form of 22 22 Like surface cracking, sir, correct? the question. 23 MR. THOMAS: Object to the form of 2.3 THE WITNESS: I don't know what he 24 the question. meant by that statement. I can't speak for him. BY MR. THORNBURGH: 25 THE WITNESS: I see that the words Page 412 Page 414 are different. Well, there are certainly changes 2 BY MR. THORNBURGH: seen by Dan Burkley in the study, correct? 3 Nevertheless, it goes on to write: 3 MR. THOMAS: Object to the form of 4 We previously had implanted Prolene suture into 4 the question. 5 dogs, and explants after ten years revealed no 5 THE WITNESS: Surface changes were changes in the material. б б observed. 7 7 BY MR. THORNBURGH: That's not a true statement, is it? 8 MR. THOMAS: Object to the form of 8 Degradation was observed, correct? Q. 9 9 MR. THOMAS: Object to the form of the question. THE WITNESS: Well, as we discussed, 10 10 the question. there were some changes that were observed on the 11 THE WITNESS: As noted in the report. 11 12 surface. 12 BY MR. THORNBURGH: 13 BY MR. THORNBURGH: 13 Degradation was observed? Yes or no? 14 Q. Surface degradation, correct? 14 MR. THOMAS: Object to the form of 15 MR. THOMAS: Object to the form of 15 the question. THE WITNESS: Could you pull up that 16 the question. 16 THE WITNESS: I think that's part of 17 17 previous screen? 18 that report. 18 BY MR. THORNBURGH: 19 BY MR. THORNBURGH: Degradation in Prolene? 19 Q. Yes. 20 So that's not a true statement, that 20 A. 21 Ethicon had not seen changes in the material, in the The e-mail goes on by Dr. Divilio, ten-year data, correct? 22 who says: I am wondering if the effects that 22 23 MR. THOMAS: Object to the form of Ramshaw, et al., are seeing are due to the abrasions of fiber against fiber in a mesh construct due to 24 the question. 25 THE WITNESS: Well, where there were flexing that occurs after implantation, trauma to

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Page 415 Page 417 the mesh as a result of implantation from a patient, don't understand the question. Object to the form or actual oxidation. I think it's important that we of the question. 3 BY MR. THORNBURGH: understand what they're seeing, as this group has a well-funded lab that will be looking at explanted 4 You're talking about generic with 5 mesh in great volume over the next couple of years, 5 respect to additive packages. You'd agree that the and our current concepts are going to be challenged. 6 Prolene that was used in the seven -- the five-year, 7 7 Do you see that there? ten-year results, and the seven-year, ten-year dog 8 A. Yes. 8 results also had the antioxidant additives, correct? 9 9 Q. Do you recall this e-mail? Yes, and I believe the additive 10 No, I do not, although it's important 10 package is what prevented a loss of molecular weight A. to note that they're talking about Bard Composix 11 11 and tensile strength. mesh, which is a multi-component mesh, and it's not 12 12 It didn't prevent surface Q. Prolene polypropylene mesh. 13 degradation, did it? 13 14 14 Q. Well, you're familiar with the MR. THOMAS: Object to the form of 15 Costello studies that found degradation of the 15 the question. 16 THE WITNESS: Well, there is evidence 16 polypropylene, correct? 17 MR. THOMAS: Object to the form of 17 that it did not. 18 the question. 18 BY MR. THORNBURGH: 19 BY MR. THORNBURGH: 19 Q. So Dr. Dieter -- am I pronouncing his 20 You understand that Costello was 20 name correctly? 21 working with the Ramshaw group? 21 Dieter Engel. A. 22 22 MR. THOMAS: Object to the form of Q. Dieter Engel? Dr. Engel, he's a 2.3 doctor from Germany, right? 23 the question. 24 THE WITNESS: I am trying to recall 24 He was head of the R&D group for a 25 the detail. Let's look at the Costello paper. 25 while. Page 416 Page 418 1 BY MR. THORNBURGH: 1 Q. For Ethicon, correct? 2 2 A. Well, I'm just asking you -- we'll Yes. 3 look at the Costello paper. 3 And Dr. Engel, on July 6, 2007, 4 A. Okay. Okay. responds. And you're copied on this e-mail, right? 5 I'm asking you: Are you aware 5 Do you see that? 6 sitting here right now, based on your memory, A. Yes. б 7 7 whether or not the polypropylene in the Costello Q. Tom, thanks for checking back and 8 study showed evidence of surface degradation? 8 asking for my scientific perspective. 9 MR. THOMAS: Object to the form of 9 There have been a number of anecdotal reports that polypropylene mesh shows some changes 10 the question; scope. 10 THE WITNESS: First, I thought it was in the surface with time, including Ethicon's own 11 11 internal studies. 12 12 the Bard product. You can correct me --BY MR. THORNBURGH: 13 Correct? 13 14 Q. Polypropylene. My question to you is 14 MR. THOMAS: Object to the form of 15 15 polypropylene. the question; scope. THE WITNESS: Anecdotal reports? Polypropylene -- polypropylenes are 16 16 not generic substances. They're very different, 17 BY MR. THORNBURGH: 17 18 depending on an additive package that's required to 18 You'd agree that the seven-year -provide stabilization, manufacturing process, aid, 19 the five-year data and seven-year data from the 19 20 so on and so forth. So I would not equate Prolene ten-year dog studies isn't anecdotal; that's an polypropylene with any other manufacturer's 21 actual scientific experiment that found surface 21 polypropylene. 22 degradation. Correct? 22 23 Q. Like the additive package in the 23 A. Yes. There were observations of 24 Prolene? 24 surface cracking and degradation. Dr. Engel goes on to say the Aachen 25 MR. THOMAS: What's the question? I 25

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Page 419 Page 421 group -- which would include Doctors -- Professors tests in-house with accelerated aging, too, and Klinge and Klosterhalfen, right? found microscopic changes in the surface of the mesh 3 3 Yes. They were with the Aachen group fibers. A. 4 for some time. 4 So there are additional studies 5 5 according to Dr. Engel of -- by Ethicon which also O. The Aachen group, who has so far 6 collected more than a thousand explanted meshes, showed surface degradation, correct? 7 7 showed examples many years back. Do you see that? MR. THOMAS: Object to the form of 8 A. Yes. 8 the question. 9 9 Q. You understand, don't you, that the THE WITNESS: Yes. He's talking Aachen group, including Klinge and Klosterhalfen, 10 about accelerated aging in conditions of increased 10 were consultants paid by Ethicon to evaluate 11 11 temperature with the intention to increase any polypropylene meshes, don't you? 12 impacts of aging. 12 13 13 MR. THOMAS: Object to the form of BY MR. THORNBURGH: 14 14 the question. Q. Did you include any of those in-house 15 THE WITNESS: That's my 15 accelerated aging studies in your list of studies regarding degradation that found microscopic changes 16 16 understanding. BY MR. THORNBURGH: in the surface of the mesh? 17 18 18 Q. And when -- during the time that A. I am not aware of them. I did not 19 Dr. Klosterhalfen was a consultant for Ethicon, he 19 include it in any of these documents. 20 evaluated a thousand explanted meshes which also 20 In fact, you did not include those 21 showed degradation? 21 studies in your material related to this question of 22 22 MR. THOMAS: Object to the form of degradation, did you? 2.3 MR. THOMAS: Object to the form of 23 the question. 24 BY MR. THORNBURGH: 24 the question; asked and answered. 25 Do you understand that, sir? 25 THE WITNESS: I just said that. I Q. Page 420 Page 422 These are human -- I am understanding iust said that. that they're human explants that he's then 2 BY MR. THORNBURGH: 2 3 investigated. I don't know who the manufacturers 3 Q. Why didn't you include those studies were, what products they were, but I see the 4 in your list --5 statement, and it stands as is. 5 MR. THOMAS: Object to the form of б 6 Human explants evaluating who? the question. Q. 7 7 Human explants will provide more BY MR. THORNBURGH: 8 reliable clinical evidence, both of degradation and 8 -- or in your binder regarding the 9 the materials than your animal studies, won't they? 9 statement or the claims by Ethicon that the Prolene MR. THOMAS: Object to the form of in the TVT will not degrade? 10 10 the question; scope. 11 The literature searches conducted 11 12 that form the basis for the documents that are 12 THE WITNESS: No. No, I do not 13 believe that, because, typically, these are meshes compiled here were a search of the Ethicon corporate 14 or products explanted for a particular reason. R&D central files. I was not aware of any studies Likely, they failed. It could be an infected site. 15 done in Germany that might have impact or contribute 15 The best way in a preclinical way to knowledge about these topics. If I had, they would 16 understand the intrinsic characteristics of 17 have been included. 17 18 materials is to implant them in very controlled 18 Q. They're not included, correct? 19 animal model systems. MR. THOMAS: Object to the form of 19 20 BY MR. THORNBURGH: 20 the question; asked and answered. 21 Did you ever look at any explanted 21 BY MR. THORNBURGH: Q. 22 meshes from humans? 22 You haven't even had a chance to Q. 23 No, other than photographs or photo 23 review those studies, have you? 24 micrographs and publications discussing such cases. 24 Well, the first question is that I Dr. Engel says: We did different 25 have not -- they're not included. 25

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Page 423 Page 425 BY MR. THORNBURGH: 1 And the second, I've not reviewed 2 2 Well, this would certainly indicate them. 3 MR. THORNBURGH: Counsel, I'd like 3 that Dr. Engel is requesting that no additional 4 production of these in-house studies that showed 4 studies be done to generate extra data, correct? 5 microscopic changes in the surface of the mesh 5 MR. THOMAS: Object to the form of fibers using the accelerated aging method. 6 the question. 7 7 MR. THOMAS: As I told you yesterday THE WITNESS: Yes. And with good 8 at the conclusion of the deposition, if you'd remind 8 reason. 9 9 me what you've asked me for, we'll respond BY MR. THORNBURGH: 10 appropriately. 10 Because you already knew that the 11 11 MR. THORNBURGH: I had to make a note surface layer of Prolene polypropylene is so I could remember to remind you to produce those. 12 12 susceptible to surface degradation, correct? MR. THOMAS: I won't do it unless you 13 13 MR. THOMAS: Object to the form of 14 14 remind me. I'll forget. the question. 15 MR. THORNBURGH: Well, they should 15 THE WITNESS: No. He says we 16 16 have been produced already. understand the mechanism pretty well. No need to do 17 MR. THOMAS: Please. further studies. BY MR. THORNBURGH: 18 MR. THORNBURGH: Well, they should 18 19 have. 19 Q. Because Ethicon already knew that the 20 BY MR. THORNBURGH: 20 surface layer of Prolene polypropylene is 21 We did different tests in-house with 21 susceptible to surface degradation, correct? 22 22 accelerated aging, too, and found microscopic MR. THOMAS: Object to the form of 23 changes in the surface of the mesh fiber. 23 the question. 24 What is happening is related to the 24 THE WITNESS: Yes. 25 specific stretching of the fibers when producing BY MR. THORNBURGH: Page 424 Page 426 sutures. As you know, you have to stretch the 1 What is the future? We will change fibers to a very high degree to get the required the material of our mesh and move to Pronova as the 2 3 breaking strength. That leads to a very high 3 future material platform for mesh. Pronova has a orientation of the polymer chains and, in turn, 4 reduced foreign body reaction compared to Prolene, makes the surface, the outer fibrils of material as shown in several animal studies. relatively susceptible to damage from mechanical б Did you include the animal studies б 7 7 that showed that Pronova has a reduced foreign body stress. 8 Do you see that? 8 reaction compared to Prolene in any of the studies 9 A. Yes. you list in any of the binders that you brought with You haven't looked at those studies, 10 Q. 10 you today? have you? 11 MR. THOMAS: Object to the form of 11 12 12 A. the question; scope. 13 Q. He goes on to write: All in all, I 13 THE WITNESS: Yes. I've included 14 believe we understand the mechanism pretty well and 14 three studies, one looking at Pronova suture wouldn't suggest to generate extra data. 15 compared to Prolene suture and Dormier repair in 15 Do you see that? rabbits, intramuscular implantation study for six 16 17 months in rats, and ophthalmic tissue reaction 17 A. Yes. 18 Q. Were you told by Ethicon -- you were 18 studies for 90 days in rats. 19 included as part of this e-mail string. Were you BY MR. THORNBURGH: 19 told not to generate additional data regarding the 20 Do you agree that with this 20 21 potential degradation of Prolene polypropylene statement, that Pronova has reduced foreign body 21 22 meshes? 22 reaction compared to Prolene --23 MR. THOMAS: Object to the form of 23 A. No. I did not. 24 Q. -- as shown in several animal studies 24 the question. 25 conducted by Ethicon? 25 THE WITNESS: No.

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Page 427 Page 429 BY MR. THORNBURGH: 1 MR. THOMAS: Object to the form of 2 the question. You haven't considered those studies 3 THE WITNESS: I've not seen those 3 before you walked in today as the person most studies. The three studies that Ethicon has 4 knowledgeable about the tissue response and tissue 5 conducted that I just mentioned show comparable 5 reaction, correct? tissue reaction to Prolene suture. 6 MR. THOMAS: Object to the form of 7 7 BY MR. THORNBURGH: the question; scope. 8 Q. You did not include in any of your 8 THE WITNESS: Studies to support the 9 9 binders that you brought with you the several animal biocompatibility of Pronova suture were conducted in studies that show that Pronova has reduced foreign 10 comparison to Prolene suture in a standard tissue 10 body reaction compared to Prolene, did you, sir? 11 11 reaction study, a protocol, as required by ISO 12 MR. THOMAS: Object to the form of 12 10993, Part 1, and G95 FDA guidance on biocompatibility testing. 13 the question; scope. THE WITNESS: I don't know the BY MR. THORNBURGH: 14 14 15 details of these studies. Standard biocompatibility 15 And --Q. 16 studies were done looking at tissue reaction to 16 And other studies that might have 17 Pronova suture compared to Prolene. 17 been conducted for other purposes, I don't know. These studies may be surgical 18 18 They're not necessary to support the 19 functionality studies with different prototype 19 biocompatibility of -- of a Pronova suture. But 20 meshes. I don't know. I can't respond to that 20 there are other studies that that have been 21 question specifically unless I see the studies that 21 conducted. 22 22 he's making. If they provide evidence to counter 23 BY MR. THORNBURGH: 23 the study results from the three Pronova studies 24 Q. This really is a "yes" or "no" that I've just mentioned, I'll be glad to look at 25 question. 25 those. Page 428 Page 430 1 A. No. it's not. 1 So the answer to my question is that 2 You did not provide in any of the you have not considered before you walked in here Q. 3 binders that you brought with you today the studies, 3 today the Pronova studies that showed less foreign the several animal studies, that show that Pronova 4 body reaction and better biocompatibility, correct? has a reduced foreign body reaction compared to 5 MR. THOMAS: Object to the form of 5 Prolene, correct? 6 б the question; scope. 7 7 MR. THOMAS: Object to the form of THE WITNESS: I'd have to look at 8 8 those studies to make that conclusion. the question. 9 THE WITNESS: Yes. 9 BY MR. THORNBURGH: BY MR. THORNBURGH: 10 You didn't look at those studies 10 He goes on to say that Pronova will 11 before you walked in here today, did you? 11 improve the perceived biocompatibility of our mesh. MR. THOMAS: Object to the form of 12 12 Do you see that? 13 13 the question. 14 A. Yes, I see that, but don't agree. 14 THE WITNESS: No, I did not. 15 Q. Of course. 15 BY MR. THORNBURGH: We've got three studies that 16 Besides, Pronova is much less 16 A. demonstrate that the tissue reaction to Prolene 17 susceptible to mechanical damage. 17 18 suture is comparable to Prolene -- to Pronova 18 As you testified to earlier, PVDF, 19 suture. 19 which is part of the copolymer of Pronova, is a more 20 You haven't even seen the studies 20 inert, more stable material than Prolene, correct? that Dr. Engel is referring to that show that 21 MR. THOMAS: Object to the form of Pronova has a reduced foreign body reaction. 22 22 the question; scope. 23 MR. THOMAS: Object to the form of 23 THE WITNESS: Yes. 24 BY MR. THORNBURGH: 24 the question; scope. THE WITNESS: That's correct. 25 25 Q. It is much easier to process in the

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Page 431 Page 433 knitting machine, less quality issues. Do you see interface between implanted material and surrounding 2 2 3 3 MR. THOMAS: Object to the form of THE VIDEOGRAPHER: I've got to change 4 the question; scope. 4 the tape. 5 THE WITNESS: Yes. 5 It's now 1:08. Going off the video 6 BY MR. THORNBURGH: 6 record. 7 7 Did you talk to -- as the person that This concludes Volume 2, Tape 2 of 8 was designated as the person most knowledgeable 8 the videotape deposition of Dr. Thomas A. Barbolt. 9 9 under the designated topics, did you talk to (Short break.) Dr. Engel about his experience with PVDF sutures and 10 THE VIDEOGRAPHER: We're back on the 10 Prolene sutures and that Prolene sutures induce a 11 video record. It's 1:14. greater inflammatory response than Pronova or PVDF? 12 12 This begins Volume 2, Tape Number 3 13 MR. THOMAS: Object to the form of in the videotape deposition of Dr. Thomas A. 14 the question. 14 Barbolt. 15 THE WITNESS: No. 15 BY MR. THORNBURGH: BY MR. THORNBURGH: 16 Dr. Barbolt, we talked briefly about 16 17 17 Dr. Ramshaw and Dr. Costello. Do you remember that? Don't you -- you agree as a scientist 18 that generation of data that could help better 18 A. Yes. 19 answer questions, safety questions, is important, 19 Q. And your e-mail -- the e-mail that 20 20 you were included on discussed studies that were right? 21 MR. THOMAS: Object to the form of 21 done by Ramshaw's group that found degradation of 22 polypropylene? 22 the question. 23 2.3 A. Yes. THE WITNESS: That's why we have 18 binders of studies surrounding us that contain 24 Q. And you had indicated that you had studies conducted in the mid 1960s. reviewed this study, correct? Page 432 Page 434 BY MR. THORNBURGH: MR. THOMAS: Object to the form of 1 2 Q. Vast -the question. It's not in preparation for this 3 A. And continue to this day. 3 deposition. 4 Vast majority of those are suture 4 BY MR. THORNBURGH: Q. 5 5 Are you not prepared to talk about studies, correct? MR. THOMAS: Object to the form of 6 the Costello studies? б 7 7 No. That's not one of the studies the question. 8 THE WITNESS: We'd have to do the 8 that I brought with me today. 9 exercise. 9 Just so the record is clear, because BY MR. THORNBURGH: I think you were indicating that maybe it was the --10 10 11 You didn't do the exercise before you because there was a composite mesh that may have 11 12 came in here today? been studied, that you weren't aware whether or not No. I didn't think it necessary, 13 13 that was polypropylene, so I just want to point out 14 because I believe that the data that's generated for 14 in the record this conclusion. suture containing the same Prolene polypropylene 15 Overall, the results support our 15 fiber as in mesh are directly applicable and hypothesis that in vivo -- inside the body, right? 16 16 17 17 relevant. A. 18 Q. General scientific principle: The 18 Q. -- oxidation plays a role in the greater the surface area of an implanted medical 19 degradation of polypropylene. 19 device, the greater the inflammatory response. 20 Do you see that? 20 21 MR. THOMAS: Object to the form of 21 MR. THOMAS: Object to the form of 22 22 the question. the question. 23 THE WITNESS: There's some 23 THE WITNESS: Yes. And as I pointed 24 out earlier, that's not Prolene polypropylene. 24 relationship to increased surface area and increasing tissue action, because that's the That's Bard polypropylene.

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Page 435 Page 437 BY MR. THORNBURGH: weight or tensile -- tensile testing. That's the 1 2 kind of information that's useful to surgeons, not Well, it's polypropylene, 3 any other observations that might be observed but nonetheless. 4 A. There's a big difference, because as 4 don't translate into significant impact on 5 we discussed earlier, polypropylene without an 5 mechanical characteristics. 6 appropriate antioxidant package is susceptible to BY MR. THORNBURGH: 7 7 degradation. And if you add an appropriate O. That's absurd. 8 antioxidant package, it is resistant to oxidation. 8 MR. THOMAS: Excuse me. 9 9 Well, we know from the ten-year --BY MR. THORNBURGH: 10 the five-year data, from the ten-year dog study, 10 You're not even -- you're not a 11 11 Ethicon study, seven-year data from that study, the clinician, are you? Prolene polypropylene was susceptible to surface 12 12 MR. THOMAS: Please. Stop, stop. 13 13 cracking, right? Stop. 14 14 MR. THOMAS: Object to the form of Thomas, let's take a break. 15 the question. 15 BY MR. THORNBURGH: 16 16 You're not a clinician, are you? THE WITNESS: It was susceptible to 17 17 surface cracking, but it did not result in loss of MR. THOMAS: Back up. Don't tell my 18 18 molecular weight or impact on tensile strength, key witness his testimony is absurd. You can ask 19 mechanical properties of polypropylene fibers. 19 questions and get your answers, and we'll object to 20 BY MR. THORNBURGH: 20 form, but you just ask him straight questions, and 21 In this statement, in this claim in 21 you'll get straight answers. 22 the IFU, it doesn't say that the material is BY MR. THORNBURGH: 22 You're not a medical doctor, are you? 23 susceptible to surface degradation, does it? 2.3 Q. 24 MR. THOMAS: Object to the form of 24 A. That's correct. 25 25 You've never treated patients, have the question. Q. Page 436 Page 438 1 THE WITNESS: No. it does not. you? 2 This is an instructions for use. 2 A. Of course not. 3 It's trying to relay to the end user of the product 3 You've never looked at an IFU and 4 important information, and for surgeons. No matter relied on an IFU in having a risk/benefit discussion 5 surface changes -- if there's no impact on molecular 5 with patients, have you? weight or tensile strength, the surface changes are б That's not my role in preclinical. 6 A. 7 7 of no consequence. But, yet, you're here telling the Q. 8 BY MR. THORNBURGH: 8 ladies and gentlemen of the jury that information 9 This is important -- the IFU provides 9 about the surface degradation of Prolene that's important information to physicians, correct? implanted permanently in women -- women's pelvises, 10 10 11 MR. THOMAS: Object to the form of 11 is not important? 12 12 the question; scope. MR. THOMAS: Excuse me. BY MR. THORNBURGH: 13 BY MR. THORNBURGH: 13 14 Q. That's what they just said, right? 14 Q. That's the position that you took? 15 A. It's intended to relay to the end 15 MR. THOMAS: You're arguing with the users, the surgeons, information that they would 16 witness. 16 17 17 find most useful. MR. THORNBURGH: I am not. 18 O. And Ethicon did not relay any 18 MR. THOMAS: Yes, you are. And we're information to the physicians in this IFU that the 19 not going to argue with him. And I object to the 19 Prolene in the TVT mesh is susceptible to surface 20 form of the question. 20 21 degradation, did they? 21 BY MR. THORNBURGH: 22 MR. THOMAS: Object to the form of 22 You're taking the position on behalf Q. 23 the question. 23 of Ethicon --THE WITNESS: That is not useful 24 24 MR. THOMAS: His position has been 25 information in light of no impact on molecular 25 taken. His answer has been given.

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Page 439 Page 441 BY MR. THORNBURGH: 1 nonresponsive. 1 2 2 You're taking the position --MR. THOMAS: Did you finish your 3 3 MR. THORNBURGH: Dave, you can answer? Did you finish your answer? 4 object. 4 THE WITNESS: Yes. 5 5 MR. THOMAS: Okay. Thank you. MR. THOMAS: You're asking the same 6 6 BY MR. THORNBURGH: question three times. 7 7 MR. THORNBURGH: Dave, you can You defer to a clinician about 8 object. 8 whether or not surface degradation is important 9 9 MR. THOMAS: I can stop the information that they need when having a risk/benefit discussion with their patients, 10 deposition, too. 11 11 MR. THORNBURGH: Dave, you can correct? 12 12 A. I think a preclinical scientist will object. 13 always defer to a clinician in making those 13 BY MR. THORNBURGH: 14 14 Mr. Barbolt, you're taking this judgments with patients. 15 position as the company spokesperson for Ethicon 15 Q. You made a statement earlier, general 16 16 that information about surface degradation is not scientific principle, that medical devices with a 17 important to clinicians when they're relying on the larger, greater surface area will have a greater 18 information for use and having risk/benefit 18 inflammatory response than one with a lower surface 19 discussions with their patients who will be 19 area. Do you remember that statement? 20 implanted with this medical device for the rest of 20 Yes. And let me --A. 21 21 their lives in their -- in and around their sexual Q. General scientific principle, right? 22 22 and reproductive organs. That's the position? A. Right. And let me remind you. It's 23 MR. THOMAS: Object to the form of 23 a general scientific principle. And the exact 24 the question; scope. tissue reaction to an implant needs to be determined 25 THE WITNESS: The IFU is not the by an implantation study, the results of which will Page 440 Page 442 responsibility of folks in preclinical. The IFU is overrule any general scientific principle and will 2 2 rely on the specifics of real and actual data put together by regulatory and medical professionals gathering input from all areas of manufacturing, 3 generated from a study. preclinical, physical testing, whatever is necessary 4 And in this study regarding surface in their minds to provide the most useful area, these investigators, who actually, by the way, information to the end users as possible. б study degradation, found that degradation -- that in б 7 7 vivo oxidation plays a role in the degradation of BY MR. THORNBURGH: 8 So would you defer to a clinician 8 polypropylene hernia mesh materials and that there about whether or not information about surface 9 may be a difference in the degree of oxidation degradation of products that are being implanted 10 between a heavyweight material and a lightweight 10 permanently in and around the sexual and 11 material because of a reduced inflammatory response. 11 12 12 reproductive organs of women is important Do you see that? 13 information to have? 13 MR. THOMAS: Object to the form of 14 MR. THOMAS: Object to the form of 14 the question. 15 15 THE WITNESS: This is not an Ethicon the question; scope. THE WITNESS: Would I defer to 16 16 product. clinicians to make that judgment? With the 17 BY MR. THORNBURGH: 17 18 information that's been provided in this case by 18 Q. That wasn't the question. 19 I am here to talk about Ethicon preclinical relating to three things in that study; A. 19 20 one, observations of surface degradation; two, 20 products. 21 quantitative measurements of molecular weight; and, 21 Q. Polypropylene is contained within 22 three, quantitative measures of tensile strength. 22 Ethicon products, correct? 23 Molecular weight and tensile strength 23 As I indicated earlier, all 24 testing indicate there's no evidence of degradation. polypropylenes are not the same. Polypropylenes 25 MR. THORNBURGH: Move to strike; with no additive package are susceptible to

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Page 443 Page 445 record. It's 1:34. oxidation. And I got to imagine that polypropylene 2 resin with varying kinds of antioxidant packages BY MR. THORNBURGH: would have varying protective actions against 3 Dr. Barbolt, you've also been 4 4 oxidation. designated by Ethicon to discuss or testify 5 5 regarding the specifics of all testing related to O. These are antioxidants that you testified earlier that there's evidence that those the TVT products during the design and development 7 7 additives leach out of the polypropylene that's used stages, including but not limited to leaching, 8 in the TVT devices, correct? 8 correct? 9 9 MR. THOMAS: Object to the form of A. 10 MR. THOMAS: Do you want those 10 the question. THE WITNESS: Yes. I think there's 11 11 notebooks now? 12 evidence that they leak out. 12 MR. THORNBURGH: I don't know that we 13 13 BY MR. THORNBURGH: necessarily need all of them, so why don't we -- why 14 14 And would you agree that there would don't we move forward, and if we need them, we'll --15 be a difference in the degree of oxidation between a 15 THE WITNESS: Let me get this first 16 16 heavyweight material and a lightweight material one, which is an index. They're -- the index is all because of the reduced inflammatory response as a 17 17 the same. BY MR. THORNBURGH: result of a reduction in the surface area that we 18 18 19 discussed earlier? 19 Q. So let's -- first let's talk about 20 MR. THOMAS: Object to the form of 20 the submission to the FDA, October of 1997, the 21 the question; scope. 21 five -- the 510(k) for the TVT-Retropubic. 22 22 THE WITNESS: It's a theoretical --Did you bring that with you today? 23 it is a theoretical discussion. 23 MR. THOMAS: Maybe. Do you have one 24 BY MR. THORNBURGH: 24 handy? 25 Yes or no? 25 MR. THORNBURGH: I think I do. Q. Page 444 Page 446 I don't know what materials they're THE WITNESS: Do you want to bring up talking about. I don't know what additive packages 2 2 the --3 they're talking about. 3 MR. THOMAS: Let him give you one. 4 How about polypropylene? 4 THE WITNESS: Okay. Okay. Q. 5 MR. THOMAS: Excuse me. Let's slow 5 BY MR. THORNBURGH: down a little bit. You're running into each other, б It's been premarked as Exhibit 6 7 7 and the record is terrible, and I don't get a chance Number T-2017. The Bates number is to object, and I need my chance to object. Let's 8 ETH.MESH.00019863. slow down so everybody gets a chance to say what 9 Now, before I get into the discussion they need to say. 10 about the topics and studies regarding leaching --10 11 MR. THORNBURGH: I'll withdraw and 11 MR. THOMAS: I'm sorry. This begins 12 12 move to strike everything after, it's a theoretical with Attachment 5. And the bottom of it says Page 3 discussion. 13 of 69. Do you know if this was the complete --13 14 MR. THOMAS: Excuse me. I need to 14 MR. THORNBURGH: Oh, you know what? 15 15 Sorry. I may have given you the wrong -say something. I said the record is terrible. I If you want to give that back to me. 16 16 should have said we risk creating a terrible record, 17 I am not exactly sure what I just handed you there. 17 18 because I am confident that our court reporter is 18 MR. THOMAS: Me either. 19 doing absolutely the best that she can. BY MR. THORNBURGH: 19 20 MR. THORNBURGH: Off the record for a 20 Okay. Let's do this again. I am 21 going to hand you what's been premarked as Exhibit 21 moment. 22 THE VIDEOGRAPHER: Off the video 22 Number 2105, which is related to the 510(k) 23 record, 1:26. 23 submission regarding the TVT-Retropubic system. 24 MR. THOMAS: May I have one, please? 24 (Short break.) 25 25 THE VIDEOGRAPHER: Back on the video MR. THORNBURGH: Yes.

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Page 447 Page 449 1 MR. THOMAS: Thank you. This one is about this before. 2 highlighted. Is it supposed to be? BY MR. THORNBURGH: 3 3 MR. THORNBURGH: That's okay. Correct? Q. 4 4 BY MR. THORNBURGH: And as I indicated before, there were 5 5 three endpoints in that experiment that are Now, this is a submission that O. 6 Ethicon made to the FDA regarding the TVT device, important: Subjective observations, observations by 7 7 a human being about what's on the surface of the correct? 8 A. Yes. That's what it looks like. 8 suture, and then quantitative assessments of 9 9 Q. And before we get into a discussion molecular weight, and quantitative assessments of about the cytotoxicity testing and the leaching 10 tensile strength. 10 issues, I just want to turn your attention to 11 11 In terms of surface changes, surface ETH.MESH.00371515. 12 changes were reported. In terms of molecular weight 12 13 A. 515. 13 and tensile strength, no impact on either of those 14 parameters, which would lead one to conclude that Okay. 14 15 Now, this is the statement that we've 15 there's no evidence of degradation that's Q. 16 discussed over the last two days regarding minimal meaningful. 16 inflammatory transitory tissue reaction and that the 17 MR. THORNBURGH: Move to strike; 17 material is not absorbed, nor is it subject to 18 18 nonresponsive. 19 degradation. Right? 19 BY MR. THORNBURGH: 20 A. 20 Sir, do you think it's okay for Yes. 21 21 Q. Now, the statement, the material is Ethicon to misrepresent information in a 510(k) 22 not absorbed, nor is it subject to degradation or submission to the FDA regarding surface cracking? weakening by the action of tissue enzymes, was 23 MR. THOMAS: Object to the form of 23 provided to the FDA in the 510(k) submission on 24 the question. 25 October 29, 2007, correct? 25 THE WITNESS: I don't think they've Page 448 Page 450 MR. THOMAS: Object to the form of done that. BY MR. THORNBURGH: 2 the question; scope. 3 THE WITNESS: 2007? 3 Regarding surface degradation? 4 BY MR. THORNBURGH: 4 MR. THOMAS: Object to the form of 5 I'm sorry. October 29, 1997. 5 Q. the question. Correct? б б THE WITNESS: I do not think they've 7 Okay. That would be the time of the 7 Α. done that. submission of the 510(k) for TVT original or 8 8 BY MR. THORNBURGH: 9 retropubic. 9 This statement says the material is Right. So October 29, 1997 Ethicon 10 not subject to degradation. 10 submitted to the FDA the 510(k) submission related 11 That's what it says, right? 11 to the TVT-Retropubic, correct? 12 MR. THOMAS: Object to the form of 12 13 A. Yes. 13 the question. 14 And in that submission. Ethicon 14 THE WITNESS: I've already explained stated that the material is not absorbed, nor is it 15 15 that the IFU is not the responsibility of subject to degradation. preclinical science. Preclinical scientists provide 16 Do you see that? information to regulatory folks and medical affairs 17 17 18 A. Yes. 18 people and clinicians, their findings. And those folks put together the most useful information for 19 But as we've already established, by 20 1990 and 1992, Ethicon was aware from its own 20 the end user, the surgeon. internal studies that the Prolene in the TVT was 21 BY MR. THORNBURGH: 21 subject to surface degradation, correct? 22 It would be inappropriate for the FDA 22 23 MR. THOMAS: Object to the form of to permit -- to misrepresent information about 24 degradation to the FDA, wouldn't it? 24 the question. 25 25 THE WITNESS: We've talked a lot MR. THOMAS: Object to the form of

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Page 451 Page 453 the question. 1 contact with, correct? 2 THE WITNESS: I don't think they've 2 MR. THOMAS: Object to the form of 3 3 done that. the question. 4 4 BY MR. THORNBURGH: BY MR. THORNBURGH: 5 5 Well, the 1990 and 1992 internal O. There's a question pending. Ο. 6 MR. THOMAS: He's answered this same studies showed surface degradation of the Prolene 7 7 mesh, did it not? question twice today. 8 MR. THOMAS: Object to the form of 8 THE WITNESS: First -- first, I've 9 9 the question. not seen the peeling that you're talking about. 10 THE WITNESS: I've already 10 And, second, all the data that we've 11 11 explained -brought here today, some 49 reports, suggest that BY MR. THORNBURGH: 12 the tissue reaction to Prolene polypropylene suture 12 13 Q. Yes or no? in mesh is relatively mild and in some cases reduces 14 14 A. I've already explained the -- my in severity over time. 15 reasonings of this in answering this question on a 15 So if there are any peeling off of number of occasions. And I can only conclude that 16 pieces of the suture, as you would suggest, it's not 16 the regulatory folks and clinical folks took the sum having an impact on the tissue action. 17 18 18 total of the results from that study and said, you BY MR. THORNBURGH: 19 know what? There's no impact on molecular weight. 19 Q. We saw in the Postlethwait paper that 20 There's no impact on tensile strength. So there's 20 even minute fragments can cause independent 21 no degradation. And that is what is reflected in 21 inflammatory responses, right? 22 22 this IFU. MR. THOMAS: Object to the form of 23 23 That statement, sir, that you just the question. 24 made is inconsistent with the conclusions by the 24 THE WITNESS: The macro fragments Ethicon employee who wrote that degradation in 25 that's discussed in the Postlethwait paper are not Page 452 Page 454 Prolene is still increasing, right? the same as what you're describing comes off the 1 2 MR. THOMAS: Object to the form of surface of a Prolene fiber, which we've not seen any 3 the question. of that in the images that we've discussed today. 4 THE WITNESS: All degradations are 4 BY MR. THORNBURGH: 5 not created equal. Degradations that are important So Ethicon chose not to warn doctors are changes in molecular weight and tensile 6 or disclose to the FDA that the Prolene mesh is 6 7 7 strength. Anything less than that is uneventful subject to surface degradation, correct? trivial response, a trivial change, that has no 8 MR. THOMAS: Object to the form of impact on important mechanical characteristics like 9 the question; scope. 10 the tensile strength. 10 THE WITNESS: Ethicon is trying to BY MR. THORNBURGH: 11 provide to the surgeons the totality of the result 11 12 Do you think -- do you think that and the most significant result that they would be 13 surface degradation of Prolene mesh would be concerned about, and that is a breakdown of the 14 unimportant to the FDA? polymer chains, which would be reflected in a loss 15 MR. THOMAS: Object to the form of 15 of molecular weight and a loss of tensile strength, which would not be useful for a suture, a single 16 the question. THE WITNESS: Yes, as long as there 17 strand suture, that's used for cardiovascular 17 18 were no impact on tensile strength and no impact on 18 repair, of which surgeons rely on to maintain its 19 19 tensile strength for the life of the patient. tissue reaction. 20 BY MR. THORNBURGH: 20 BY MR. THORNBURGH: 21 21 You have to agree with me, sir, that Q. Are you done, sir? Are you done, 22 if the material is peeling away and coming off of 22 sir? the Prolene fibers, that those -- those shards that 23 Dr. Barbolt, are you finished? peel away will increase or by itself cause an 24 A. Yes. 25 inflammatory response to tissue that it comes in MR. THORNBURGH: Move to strike;

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Page 455 Page 457 nonresponsive. 1 wrote. 2 BY MR. THORNBURGH: 2 MR. THOMAS: I don't think he -- I 3 3 don't believe he cut and pasted. Ethicon chose not to warn doctors or MR. THORNBURGH: Well, now you're to disclose to the FDA that the Prolene mesh is 4 5 5 subject to surface degradation in their 510(k) doing another speaking objection. 6 6 MR. THOMAS: You asked him about this submission, correct? 7 7 MR. THOMAS: Object to the form of at length in his last deposition. That's why I 8 the question; scope. 8 remember it so well. 9 9 He's not designated on this, Dan. MR. THORNBURGH: Well, the subject 10 THE WITNESS: It's not in this action 10 matter that he's been designated to discuss is 11 section. 11 leaching, which is covered by -- which is part of 12 BY MR. THORNBURGH: 12 the cytotoxicity, is it not? 13 MR. THOMAS: But you've asked him 13 Q. If I can turn your attention to Bates 14 Number ETH.MESH.00371544, this is the 14 what he's done personally so far, and you've covered 15 biocompatibility test results, correct? 15 this at length at the last deposition. 16 16 Go ahead. It's your deposition. A. Yes. 17 17 BY MR. THORNBURGH: Q. And you drafted this, didn't you? 18 This is likely cut and paste from a 18 Sir, are you prepared -- did you 19 document that I would have provided, and it's part 19 prepare for this 30(b)(6) deposition to discuss the 20 20 cytotoxicity testing that was done at Ethicon? of a 510(k) submission. This looks like my 21 21 Are you the person most knowledgeable language. 22 22 Q. And on Page 41, ETH.MESH.00371545, and have you been prepared on that subject for this there's a discussion about cytotoxicity testing that 2.3 23 30(b)(6) deposition? was performed by Ethicon through NAMSA under the 24 MR. THOMAS: He's been designated on ISO 10993-5 guidelines which showed that 25 the topic as identified in the notice, and leaching Page 456 Page 458 polypropylene mesh was moderate to severely is one of the topics, and cytotoxicity comes within 2 cytotoxic in vitro, correct? 2 that topic. 3 A. Yes. 3 MR. THORNBURGH: Okay. 4 Q. 4 BY MR. THORNBURGH: And the polypropylene mesh component of the sterile sheet -- this is apparently what you 5 Now, sir, I know that you're here. 5 б You've been designated by Ethicon as a company wrote -- the polypropylene mesh component of the 6 7 sterile TVT device was cytotoxic, and only the 7 spokesperson to discuss this issue. Elution test suggesting cytotoxic potential in this 8 Were you the person who wrote this 9 sensitive test system. 9 section of the biocompatibility testing results? So you would agree with me that based 10 10 I'm not certain, but it's likely. on the Elution test, there was evidence of 11 And you wrote that: The long history 11 Q. 12 cytotoxicity in vitro, correct? of safe clinical use of polypropylene as mesh in 13 A. Yes. suture products suggest strongly that the material 14 O. And then you wrote: However, the is inherently biocompatible and that the potential long history of safe clinical use of polypropylene 15 cytotoxicity observed is self-limiting. 15 as mesh and suture products suggest strongly that 16 What did you mean by "self-limiting"? 16 17 17 this material is inherently biocompatible, and the Not progressive beyond the 18 potential cytotoxicity observed is self-limiting. 18 implantation period. Something that's not likely to 19 What do you mean by "self-limiting"? 19 exacerbate a tissue reaction response. 20 MR. THOMAS: Object to the form of 20 You'd agree with me that cytotoxicity, even at the implant level, could 21 the question; scope. 22 increase the inflammatory response, right? 22 Have you established that he wrote 23 this part? 23 MR. THOMAS: Object to the form of 24 24 MR. THORNBURGH: He said -- I thought the question. 25 he said it was cut and pasted from something he 25 THE WITNESS: Yes. If there's death

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Page 459 Page 461 of cells, and it's simply cytotoxicity, if there's information as you see here, and they made the death of cells in the tissue surrounding the judgment. I am not sure how -- how that went, where implant, it's very likely to increase the tissue it went, and where they went to get information, but 4 reaction. they had access to this information. 5 BY MR. THORNBURGH: 5 BY MR. THORNBURGH: And some of the symptoms that you 6 And that's despite the fact that your 7 would expect to see if a mesh material or the 7 study showed the potential, at least in vitro, for 8 additives in the mesh material were cytotoxic would 8 cytotoxicity, correct? 9 be delayed wound healing and ulcerations, correct? 9 MR. THOMAS: Object to the form of 10 Well, certainly delayed wound healing 10 the question. 11 and increased tissue reaction. 11 THE WITNESS: Yes. Yes. And at the 12 The relationship to ulceration is not 12 same time, as I've indicated here, they've relied on a direct one. It doesn't usually happen. However, 13 13 clinical data in ETH.MESH.00371546 to address any it can occur in some animal studies because of the 14 14 potential in vivo cytotoxicity by talking about 15 nature of animals. But the two key endpoints would 15 their experience in the field. be increased tissue reaction and delayed wound 16 16 BY MR. THORNBURGH: 17 healing response. 17 In fact, I'm going to go ahead and --And in the actions animal section of 18 18 O. I am going to give you what's been premarked as 19 the IFU --19 T-3185. 20 20 Who's Cary Linsky? MR. THOMAS: What page are we, 21 21 please? I think he was the project leader for A. 22 22 MR. THORNBURGH: ETH.MESH.1515 of the TVT original. 23 exhibit, 2105. 23 MR. THOMAS: Just for the record, 24 BY MR. THORNBURGH: 24 this is marked 3186? 25 In the action section in the animal 25 MR. THORNBURGH: I'm sorry. Yes. Page 460 Page 462 section of the IFU, there is no disclosure to Premarked Exhibit 3186. 2 physicians that there is evidence in vitro tests of 2 BY MR. THORNBURGH: 3 cytotoxicity associated with the Prolene mesh in 3 Q. And this is dated 9/11/97, correct? 4 TVT, correct? 4 A. Yes. 5 MR. THOMAS: Object to the form of 5 And this discusses how there was a 6 б decision to delay the TVT device from August to the question; scope. 7 7 THE WITNESS: I don't see it here. September as a result of the cytotoxicity results 8 8 but as I indicated before, for end users -- and, from NAMSA, correct? again, this is not a preclinical document. 9 MR. THOMAS: Object to the form of Preclinical folks provide information for the people 10 10 the question; scope. responsible for this document. 11 11 THE WITNESS: I would have to read 12 But in the absence of increased 12 this document. I've not seen this before. 13 tissue reaction and in the absence of impact on 13 Yeah. I see that. I totally agree. 14 wound healing, there's no need to put additional 14 BY MR. THORNBURGH: 15 information in the action section. So that would be 15 It says: The TVT data is vitally 16 my recommendation. And, again, it's the clinicians 16 important for two reasons. It is the only 17 and regulatory folks who make the final call. 17 functionality data we have, i.e., no animal studies. 18 BY MR. THORNBURGH: 18 Two, the toxicity position paper draft heavily relies on the clinical data to place in perspective 19 19 Did you make that recommendation --20 did Ethicon make that recommendation or did you make 20 the cytotoxicity profile of the device. 21 that recommendation to the individuals who were 21 For the above reasons, we need to 22 deciding on what language goes into the IFU? 22 have good assurance for the integrity of the data 23 MR. THOMAS: Object to the form of 23 that we put into our submission. 24 the question. 24 Do you see that? THE WITNESS: I provided the 25 25 Yeah, absolutely. I totally agree.

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Page 463 Page 465 1 Okay. So there was already a 1 MR. THOMAS: Object to the form of toxicity position paper that was drafted before the the question; scope. 3 clinical data was even available? THE WITNESS: No, I do not know that. 4 MR. THOMAS: Object to the form of 4 BY MR. THORNBURGH: 5 5 the question; scope. Do you know how much money -- what 6 BY MR. THORNBURGH: the financial interest was for Ulmsten, who was the 7 7 inventor of TVT, that the results would be Q. Right? 8 A. Well, the toxicity position paper is 8 favorable? 9 9 independent of any clinical data. It was based on a MR. THOMAS: Object to the form of compilation of all the cytotoxicity studies that 10 10 the question. were conducted previous to the 510(k) submission and 11 11 THE WITNESS: No, I do not. 12 for the 510(k) submission. 12 MR. THOMAS: Scope. So that happens -- that's a 13 13 BY MR. THORNBURGH: 14 preclinical issue that happens independent of 14 Do you know how much Ethicon was 15 clinical. 15 paid, or are you prepared to testify how much 16 16 Ethicon paid to Ulmsten throughout the years for And the clinical data that Ethicon 17 was waiting on before submitting the 510(k) positive results in the Scandinavian multi-center 18 submission with your biocompatibility assessment was 18 trial? 19 the Scandinavian multi-center trial, right? 19 MR. THOMAS: Object to the form of 20 MR. THOMAS: Object to the form of 20 the question; scope. 21 21 THE WITNESS: I have no knowledge of the question; scope. 22 22 THE WITNESS: Yes. That's what it that information. says. They need to finalize that data. 2.3 BY MR. THORNBURGH: 23 24 MR. THOMAS: Wait a minute. He's 24 I've just handed your counsel 25 asking you whether you know this, not what you're opposite an exhibit marked as 2254. Page 464 Page 466 reading off the paper. 1 MR. THORNBURGH: I have a copy for 1 2 THE WITNESS: No, I'm reading it. you, Counsel. 3 MR. THOMAS: Okay. Because if he's 3 MR. THOMAS: This is the version that going to be a corporate representative, he's not 4 you've already highlighted? 5 prepared on this, and this is not part of his 5 MR. THORNBURGH: Yes, sir. designation. So if you want to -б б (Document marked for identification 7 7 MR. THORNBURGH: He refers to -- part as Exhibit T-2254.) 8 of the designation is the biocompatibility 8 MR. THOMAS: Did you say 2254? assessments. And he -- he just deferred to the 9 Thank you. clinical data available to support the non-cytotoxic BY MR. THORNBURGH: 10 10 effect or the self-limiting effect of the 11 Have you seen this document before? 11 Q. cytotoxicity in the TVT material. 12 12 A. 13 So if that's a position he just took, 13 Q. And this is a Prolene suture to which 14 then I ought to have an opportunity to cross-examine 14 surface additives had been applied or evaluated to 15 him on that issue. 15 determine their tissue response characteristic in MR. THOMAS: We've told you what he rat gluteal muscles at three, 14, and 28 days post 16 17 implantation. Do you see that? 17 has prepared to talk about cytotoxicity. This goes 18 well beyond it. I am not going to argue with you. 18 A. Yes. 19 You ask your questions, but --And the finding from this study is 19 20 BY MR. THORNBURGH: 20 that two of the additives, Lubrol PX and Santonox 21 21 Before I do, are you aware of how R -- those are antioxidants, correct? Q. 22 much money -- strike that. 22 A. 23 Are you aware that Dr. Ulmsten was 23 O. And those antioxidants, as you 24 the primary clinical researcher in the Scandinavian 24 testified previously, can leach out of the Prolene 25 multi-center trial? 25 mesh, correct?

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Page 467 Page 469 A. 1 MR. THORNBURGH: Move to strike. 1 Yes. 2 And this study found that two of the 2 O. BY MR. THORNBURGH: additives, Lubrol PX and Santonox R, elicit tissue 3 3 Q. We're going to discuss the 28-day 4 responses significantly greater than controls. Do 4 study, but my question is: Was the Lubrol and the 5 vou see that? 5 Santonox R -- will leach out of the mesh fibers, 6 6 Α. Yes. correct? 7 7 O. Did Ethicon disclose in the 510(k) MR. THOMAS: Object to the form of submission that the antioxidants that leach out of 8 8 the question. 9 their mesh when tested against negative controls 9 THE WITNESS: Yes. I've already 10 elicited a tissue response that was significantly 10 admitted that these agents can leach out. This 11 experiment is not relevant to that question. 11 greater? 12 MR. THOMAS: Object to the form of 12 BY MR. THORNBURGH: the question; scope. 13 Well, this experiment does show that 13 BY MR. THORNBURGH: 14 Lubrol and Santonox can elicit a greater tissue 14 15 15 response, correct? Q. Doctor? 16 16 Let me just read the comments Only when smeared on the surface of a A. A. Prolene suture. 17 17 section. 18 18 Okay. This is an exploratory study Now, you talk about the 28-day study. 19 where they coated the Prolene suture which already 19 Before we go there, I just have a couple questions 20 contains additives, but with additional additives on 20 for you about that, that I want to get my hands 21 the surface. 21 around. 22 22 O. To mimic leaching, right? The 28-day study that you are 2.3 No, to load up the suture with some 23 referring to is a study that compared Prolene flat A. components of the antioxidant package to see if 24 mesh raw material to the TVT finished product, there had been any impact on tissue reaction. correct? Page 468 Page 470 1 And the finding was that there was an 1 As I recall, that was Prolene flat impact on tissue reaction. There was, in fact, a 2 mesh finished goods, the final product, compared to 3 significantly greater reaction in the controls, 3 TVT mesh, final product. 4 correct? 4 Which would have also contained 5 Yes, that's the case, but it's not 5 Santonox R and Procol and Lubrol, correct? relevant to Prolene suture or Prolene mesh, because A. 6 б Yes. 7 the Prolene suture and Prolene mesh is not coated 7 Q. Okay. So you tested a mesh device 8 with additional additives like what was done in this 8 that already had additives in it to another mesh 9 experiment. 9 device which already had additives in it, correct? 10 10 Yes, that's right, the difference So it's an exploratory study to being that the Prolene flat mesh is not cytotoxic in 11 understand irritant potential of various 11 12 antioxidants, but it has no relevance to current 12 vitro, and the TVT mesh is cytotoxic in vitro. 13 production products, the suture or mesh. 13 Now, I hear what you're saying, that there were studies done of the Prolene flat mesh, 14 Well, with all due respect, sir, the 14 15 Lubrol and the Santonox R will leach out of the mesh 15 not the TVT, but the Prolene flat mesh used in 16 fibers, correct? hernia repair, that tested negative for 16 17 It's possible that they will leach 17 cytotoxicity; is that what you're saying? 18 out of the mesh fibers. I think they do. As I've 18 Yes. The same Prolene mesh that's in 19 indicated, there's evidence for that. 19 TVT mesh was negative. 20 At the same time, I've also indicated 20 Was there a NAMSA Elution test done in that set of studies similar to the Elution test 21 that in the 28-day Prolene mesh TVT mesh experiment, 21 that was done in the TVT product which found 22 there was no increased evidence of tissue reaction 22 23 indicating that if any of the additives were to 23 moderate to severely -- severe cytotoxicity?

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We'd have to look at the individual

25 studies in the 510(k), and the summaries may be

24

24 leach away, it had no impact on the surrounding

Page 471 Page 473 sufficient here, but I might need to go to the full mechanisms of cytotoxicity and a summary of the study reports in the binders that we've brought. tests that were performed by Ethicon, correct? 3 But let me take a look. 3 A. Yes. 4 4 On ETH.MESH.00371569, there is a Q. And this says that: As part of the 5 summary of the study that I am making reference to. 5 overall assessment of biocompatibility of the TVT In fact, two studies were conducted with the normal 6 device, a number of cytotoxicity studies were 7 7 production Prolene flat mesh. conducted. Right? 8 And can you give me -- I don't have 8 A. Yes. Q. 9 9 your binder. And it goes on to say: After an 10 MR. THOMAS: He's testified from your 10 evaluation of all the test results, only the polypropylene mesh component of the sterile TVT 11 exhibit. 11 12 12 device was considered to be cytotoxic, and the THE WITNESS: Yeah. It's your 13 13 exhibit. severity was moderate to severe. 14 14 MR. THOMAS: It's the 510(k). Do you see that? 15 15 Yes. 2105. A. 16 16 THE WITNESS: ETH.MESH.00371568. In the ISO Elution testing using USP O. BY MR. THORNBURGH: 17 scoring system as slight, mild moderate, and severe. 17 18 18 Q. 15 ---Now, what does it mean to be 19 A. 1568 and 1569. These were the 19 moderately cytotoxic in terms of the number of cells 20 cytotoxicity studies conducted with Prolene flat 20 that will die when they come into contact with the 21 mesh. But one, an agarose overlay, was 21 offending agent? 22 non-cytotoxic, as it was for the TVT flat mesh. Yeah. I -- I know in -- I could pull 22 A. 23 What you're referring to is the 23 up the study to find the detail. 24 second study on Page 65 of that. That's 24 MR. THOMAS: If you need to do that, 25 ETH.MESH.00371569. This is a filter paper method, a 25 do that. If you want that detail --Page 472 Page 474 little bit different than the ISO Elution method. 1 THE WITNESS: Actually, let me get 2 The ISO Elution method is taking an that detail. Let me look at a cytotoxicity study as 3 extract of the mesh and put it into contact with 3 an example. cells. In this case -- and it's a cytotoxicity 4 BY MR. THORNBURGH: 5 assay that's commonly conducted for medical devices. 5 Well, just hold on a second. You б In this case, an extract is placed on б don't know right now sitting here from your memory 7 a filter paper, which is then placed on an agarose 7 what the USP scoring system says concerning the 8 overlay. And in that study, the test article was 8 number of cells that will die when they come into 9 non-cytotoxic. 9 contact with the cytotoxic agent? That was a different method? 10 MR. THOMAS: Object to the form of 10 Q. 11 A. Slightly different. Slightly 11 the question. That's why he's prepared with all these notebooks, because he can't remember different, but very similar in that both used 12 extracts, such that if there were leachables from 13 everything. 13 14 the device, they would have gone into the extract 14 MR. THORNBURGH: Well --15 and either the extract placed in contact with the 15 MR. THOMAS: So if you want the cells or the extract pipetted onto filter paper put answer to the question, he's going to consult the 16 16 onto cells. Similar, but they're different. 17 17 study. 18 MR. THORNBURGH: Move to strike, 18 MR. THORNBURGH: Number 4 on nonresponsive, after they're slightly different. 19 leaching. 19 20 BY MR. THORNBURGH: 20 MR. THOMAS: Do you want him to look 21 21 I'll hand you what has been premarked at it? 22 as T-2132, which is a document draft entitled 22 BY MR. THORNBURGH: "Mechanisms Of Cytotoxicity In TVT Polypropylene 23 You're going to pull up some study. 24 Mesh." 24 I'm asking what under the USP system, right? 25 25 Now, this is a discussion of the It's greater than 50 percent of the

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Page 475 Page 477 cells, right? characterization person, Mr. or Mrs. Rippy? 1 2 2 MR. THOMAS: He'll check here and If it was finalized, it would have 3 3 gone to her, as well as the distribution on the make sure. 4 4 THE WITNESS: For a moderate page. 5 response, not more than 70 percent of the cells 5 That's what I'm -- I am trying to Q. 6 6 would be rounded and/or lysed, which would be understand. 7 7 evidence of cytotoxicity. Do you know if this information was 8 I should point out that a mild 8 ever provided to the product characterization 9 9 response, which is acceptable, results in not more person, Mr. or Mrs. Rippy? than 50 percent of the cells having evidence of 10 Is it Mr. or Mrs? 10 11 11 cytotoxicity. Marian. BY MR. THORNBURGH: 12 12 I do not know that. A finalized copy 13 has not been located. 13 Q. So at moderate cytotoxicity, up to 70 percent of the cells die that come into contact 14 14 Do you know what her responsibility 15 with the offending agent, correct? 15 was as the corporate product characterization person 16 A. 16 at Ethicon? Yes. 17 MR. THOMAS: Object to the form of 17 Α. She was the director of the group 18 the question. 18 that included a biocompatibility surgical 19 THE WITNESS: Yes. That's in 19 functionality, laboratory animal resources, product 20 accordance with the scheme. Not more than 70. So 20 performance evaluation, and materials 21 between 50 and 70. 21 characterization. 22 22 BY MR. THORNBURGH: O. And that role is important in 23 23 Okay. And for severe cytotoxicity, understanding the -- for future reference, 24 70 to 100 percent of the cells that come into understanding the safety and biocompatibility of contact with the offending agent die, correct? Ethicon's products, correct? Page 476 Page 478 1 A. Yes. 1 A. Yes. She was the leader of the 2 group. MR. THOMAS: Object to the form of 2 the question. 3 Q. Now, it says additional studies were 4 BY MR. THORNBURGH: 4 conducted -- it goes on to say there was another --5 And under the testing conducted by it says: However, cytotoxicity of the testing of the polypropylene raw material also used in the 6 NAMSA of the TVT finished product, between 50 and a б 7 hundred percent of the cells that came into contact 7 manufacture of Prolene indicated that it was 8 died, right? 8 non-cytotoxic. 9 A. That's correct. 9 One thing we've established is that 10 both of those -- both of those products contained Q. Now, in your mechanism of -- this is 10 Santonox and Lubrol, which we've seen are cytotoxic, your draft, right? This is your -- you wrote this; 11 11 12 12 or cause an increase in tissue response, correct? is that correct? 13 A. Yes, that's correct. 13 The Santonox R was. And I think 14 Q. And so you discuss -- who's M. Rippy? 14 there may have been a change from Lubrol to 15 A. She was a director of corporate 15 Santonox R because of a change in supplier. product characterization at that time. 16 16 I think there was a change in Lubrol Q. 17 Director of corporate product? 17 to Procol. Right? Q. 18 A. Corporate product characterization. 18 Well, no. I think the Procol LA-10 That was the preclinical sciences group. 19 19 was a non-ionic surfactant. It was a processing 20 Was there ever a final? Because I 20 aid. I believe. 21 could only find the draft. 21 And so it was the antioxidant, 22 No, I don't have a final. I have not 22 Santonox R and Procol LA-10 that had the most A. potential for in vitro cytotoxicity. 23 been able to locate a final signed copy. 23 Did you ever provide or did Ethicon 24 All right. And you discuss -- you go 24 25 on to discuss: Additional studies were conducted to 25 ever provide this document to the corporate product

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Page 479 Page 481 1 better understand the nature of the cytotoxic Were you concerned that using a heat Q. potential of the polypropylene mesh under different 2 shrink tubing -- that that additional heat that's 3 applied could cause the additives to leach to the conditions. Individual components of the 4 polypropylene resin additive package used in the surface of the Prolene mesh? 5 manufacture of the mesh were also evaluated to 5 You would call that blooming. In the Α. determine if any single additive might be package, it would be a blooming of those additives 7 7 of the surface, where in the body, it would be a contributing to the cytotoxic potential of the 8 material. 8 leaching. 9 9 Now, you say cytotoxic testing of the That was the -- that was the 10 polypropylene mesh from this device was -- resulted 10 hypothesis at the time. 11 11 in severe cytotoxicity. And so even with the low and high Do you see that study, 196? 12 12 tubing process, there's still heat being applied 13 Hang on. Let me put it into context 13 which could cause additives to bloom to the surface so that we're -- we look at this entire document. 14 of the mesh, correct? 14 15 Since there was the possibility of 15 A. That's correct. 16 16 the use of localized high temperature during And you go on to say: Cytotoxicity application of the heat shrink tubing might be 17 testing of the finished nonsterile TVT device 17 contributing to the cytotoxicity of the 18 18 resulted in slight cytotoxicity, which met USP 19 polypropylene mesh, a study was conducted using low 19 acceptability criteria. 20 temperature heat shrink tubing to manufacture the 20 You go on to say: The material 21 21 TVT device. safety data sheet for the individual component of 22 22 And so you're able to rule out the polypropylene resin additive package used to 23 use of the high shrink tubing as the cause for 23 stabilize the polypropylene mesh were evaluated, and cytotoxicity, because when you used low temperature ISO Elution cytotoxicity testing was conducted for shrink tubing to manufacture the TVT device, the some of them, using maximum concentrations of these Page 480 Page 482 studies confirmed again that there was severe materials added to the resin, and then, if necessary, at the concentration of these chemicals 2 cytotoxicity in the polypropylene mesh, correct? 3 MR. THOMAS: Object to the form of 3 which could be extracted from the polypropylene 4 the question. 4 resin by water --5 THE WITNESS: Yeah. You would 5 MR. THOMAS: By mesh. б conclude that there was either no impact or the heat б BY MR. THORNBURGH: 7 applied even to the low temperature heat shrink 7 -- polypropylene mesh by water at 8 tubing was insufficient. 8 37 degrees Celsius for 24 hours to mimic the 9 BY MR. THORNBURGH: 9 cytotoxicity extraction conditions. Right? Okay. Now, we know from two tests, 10 That's exactly right. 10 A. that it's still the TVT mesh that is cytotoxic, 11 Q. All right. And you talk about 11 right, not the process of the heat being applied to 12 another antioxidant, which is DLTDP, was tested and 12 13 the heat shrink tubing, correct? 13 found to be non-cytotoxic, right? 14 MR. THOMAS: Object to the form of 14 A. Yes. 15 15 Q. And Santonox R, another antioxidant the question. THE WITNESS: Well, there's still was tested 3 milligrams per milliliter and resulted 16 17 in severe cytotoxicity, right? 17 some heat to shrink a low temperature heat shrink 18 tubing, but not as high as for a higher temperature 18 Α. Yes. 19 19 heat shrink tubing. And then you ran that test again with 20 So that's directional information, 20 a lower volume of Santonox, which resulted from and it's -- the relevance, obviously, is that it's 21 aqueous extraction of the polypropylene mesh, right? uncertain. There's still temperature added, but, 22 A. 22 Yes. apparently, it's sufficient to cause an in vitro 23 Q. And found no cytotoxicity when you 24 cytotoxicity result. 24 lowered the level? Yes. This would be a level to 25 BY MR. THORNBURGH: 25

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Page 483 Page 485 BY MR. THORNBURGH: approximate what might come out after extracting the 2 mesh in the manner for the original cytotoxicity We'll probably look at the e-mail work. So this would -- you would conclude here that 3 first, because attached is a copy of J. Karl's memo. 4 Santonox R is not the element that is contributing Who's J. Karl; do you know? 5 5 to in vitro cytotoxicity. John Karl. A. 6 6 Santonox at .2 milligrams per And what was his position at Ethicon? Q. Q. 7 7 milliliter was found to be non-cytotoxic, right? A. Polymer engineer. 8 A. Yes. Yes, that's correct. 8 Q. Okay. And J. Karl's memo indicating 9 Santonox at 6 milligrams per 9 the R&D specifications for the various additives milliliter was -- Santonox at 3 milligrams per 10 used in Prolene resin. 10 milliliter was cytotoxic, right? 11 11 A. I've seen this. 12 Yes, and probably as much as could be 12 It says: If there is any Q. dissolved in water. It's relatively nonpolar. So 13 biocompatibility and/or safety documentation for 13 this is the maximum amount that could be 14 Prolene, it should have addressed the additives and 14 15 solubilized. 15 made some worst case estimates. 16 16 Do you see that? Then the second attempt was to 17 approximate what might come out under actual 17 Yes. A. extraction conditions, such that would occur as in a 18 18 Then there was a memo attached from 19 cytotoxicity study. 19 John Karl, an engineering fellow at Ethicon, who 20 And then you went on and tested 20 does an in-depth discussion of really the history of Q. Procol LA-10. Prolene and the manufacturing process. 21 21 22 22 You've read this document before. Do you understand that Procol and Lubrol are essentially the same antioxidant agent? 23 right? 23 24 MR. THOMAS: Object to the form of 24 Yes. I've seen this. 25 25 MR. THOMAS: When you're talking the question. Page 484 Page 486 about this document, you are talking about the THE WITNESS: I didn't appreciate 2 e-mail and the memo? that, but... 3 BY MR. THORNBURGH: 3 MR. THORNBURGH: I am talking about 4 You don't know that? 4 the memo -- the memo attached, which is 5 MR. THOMAS: Object to the form of ETH.MESH.02268619, dated January 23, 2003 addressed to Dan -- Mr. Dan Burkley at Ethicon from a Mr. John 6 б the question; scope. 7 Karl, engineering fellow from Ethicon. 7 THE WITNESS: No. I know it as a 8 BY MR. THORNBURGH: 8 Procol LA-10 here. 9 BY MR. THORNBURGH: 9 Q. You've seen this before, right? 10 I've seen the memo you've pointed Before you came here today -- before A. 10 you came here today, had you seen this document out. I don't believe I've seen the e-mail on the 11 11 authored by Dan Burkley dated February of 2003? 12 first page. 12 13 MR. THOMAS: May I have a copy of it, 13 Q. Sure. It talks about how Ethicon had basically obtained the Prolene mesh from Montecatini 14 please? 14 Company. Did I pronounce that correctly? MR. THORNBURGH: I'm sorry. We'll go 15 15 I don't know. That was well before ahead and mark it as an exhibit. 16 A. 16 BY MR. THORNBURGH: 17 my time. 17 It's been premarked as T-305. 18 18 O. Okay. It goes through, really, the in-depth background. We don't need to cover it all. 19 Is this the first time that you've 20 seen this document? But it does talk about how Prolene -- how Ethicon 21 came to purchase Prolene from the original company, 21 MR. THOMAS: Are you talking about 22 which was Montecatini, in it looks like New York --22 the e-mail or --23 it looks like the offices were in New York City. 23 MR. THORNBURGH: The e-mail and the 24 He goes on and talks about their 24 document attached to it. plant in West Virginia. And it goes on and talks MR. THOMAS: Separate documents. 25 25

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Page 487 Page 489 about some of the changes in the company, of the Lubrol and using the polypropylene form -- from a polypropylene resin was still being sold to Ethicon continuous reactor versus the original batch 3 from these various companies throughout the years. 3 reactor. 4 4 A. Yeah. I think the original supplier Do you see that? 5 5 was the Novo Mont plant, as I read this document. A. Yes. 6 And they came from -- apparently, they bought the Q. It says: We substituted Procol LA-10 7 7 resources of Montecatini. for Lubrol solely because the Lubrol became no 8 Q. It goes on to say: The objective to 8 longer available. However, prior to consummating 9 9 the substitution, we validated that the Procol was every polymer resin run has been to duplicate the original formulation as exactly possible, warts and 10 the same material as the Lubrol but from a different 10 11 11 vendor. 12 12 Do I read that correctly? Do you see that? 13 13 A. Yes. A. Yes. That's my understanding. 14 Okay. So does that help you 14 Q. Do you know what warts Ethicon Q. 15 continued to include in their Prolene resin and 15 understand that the Lubrol and the Procol are really manufacture of the TVT devices? 16 the same thing, just from a different vendor? 16 17 MR. THOMAS: Object to the form of 17 Okay. Thanks, Dan, for that 18 18 the question; scope. clarification. 19 THE WITNESS: No, although I think 19 Q. Okay. And it goes on to say the 20 that knowing John, I think what he was saying was 20 added -- it goes on and lists the additives that 21 21 we're going to keep this original formulation as it were added. 22 22 is. It says: The additive package in use 2.3 BY MR. THORNBURGH: 23 today is the same as was used in the original 24 No matter what bad things are formulation from years ago with the two exceptions 25 associated with it, right? noted above. Page 488 Page 490 MR. THOMAS: Object to the form of 1 In addition, 1991, the Santonox 2 levels were reduced slightly. Santonox is an the question; scope. 3 THE WITNESS: I can't put words in --3 antioxidant that protects the resin from thermal 4 we have to think through where he's going with this. 4 oxidation during extrusion. And that is -- and I've made this statement before. 5 So you see, actually, in 1991, after And that is we need to maintain the original б the ten-year dog study was started, that Santonox, 6 7 an antioxidant, was actually reduced from the resin. 7 formulation because we're accumulating a large database of preclinical and clinical experience that 8 Do you see that? 9 demonstrates the safety and functionality of this 9 MR. THOMAS: Object to the form of product. 10 10 the question. 11 BY MR. THORNBURGH: 11 THE WITNESS: I see the statement. Long-term clinical data from folks 12 BY MR. THORNBURGH: 12 13 like the Scandinavian folks, who were paid \$400,000, 13 So the -- the Prolene resin that was 14 as long as they -- the adverse events didn't change 14 used in the ten-year study by Ethicon actually had in their follow-up studies, correct? 15 less antioxidants in it than the sutures that are --15 MR. THOMAS: Object to the form of 16 strike that. 16 17 17 the question; scope. According to this document, the 18 THE WITNESS: Well, no. I was 18 history is correct. The Prolene sutures that were in the study conducted by Dan Burkley, the ten-year thinking of the beginnings of Prolene suture in 19 19 20 1965. 20 study, had more antioxidants than current production 21 21 BY MR. THORNBURGH: TVT, right? 22 In any case, they continued to 22 MR. THOMAS: Object to the form of 23 manufacture the same Prolene resin, warts and all. 23 the question; scope. 24 No changes have ever been made in the chemistry with 24 THE WITNESS: It says they were 25 reduced slightly. 25 the exception of substituting Procol LA-10 for

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Page 491 Page 493 BY MR. THORNBURGH: 1 1 MR. THOMAS: Object to the form of 2 2 So there's less Santonox R in the the question; scope. 3 3 THE WITNESS: This would indicate Prolene polypropylene to protect against oxidation 4 4 than existed prior to 1991, right? that. 5 MR. THOMAS: Object to the form of 5 It also indicates that when this the question; scope. This is not a designation for minor change was made, the suture extrusion 7 7 him at all. processes were fully validated to demonstrate that MR. THORNBURGH: Well, he was 8 8 no adverse effect on the suture properties resulted 9 9 designated as the person to talk about degradation from this change. and degradation studies, so I think it's important 10 MR. THORNBURGH: Move to strike; 10 11 11 for him to understand that -nonresponsive. MR. THOMAS: I am not going to argue 12 12 BY MR. THORNBURGH: 13 13 with you. There wasn't even another question 14 14 MR. THORNBURGH: -- the ten-year data pending. You've got to wait for me to ask a 15 had more antioxidants in it than -- than the TVT 15 question. 16 16 mesh. Yet, it still showed surface degradation. You were designated as the person 17 Right? 17 regarding the additives and leaching, right? MR. THOMAS: No. 18 18 MR. THOMAS: You're just not going to 19 establish that through this witness. He's not been 19 BY MR. THORNBURGH: 20 designated as a corporate representative on the 20 Leaching of additives, right? chemical composition of the mesh. 21 21 MR. THOMAS: Leaching, period. 22 THE WITNESS: I understand that I am 22 MR. THORNBURGH: He has been 23 designated for degradation. He's been designated as 23 to address biocompatibility issues related to 24 the person who will discuss -leachables, both in terms of local tissue reaction 25 MR. THOMAS: I'm not going to argue and any impact on cytotoxicity. Page 492 Page 494 1 with you. 1 BY MR. THORNBURGH: 2 2 And this would indicate that one of MR. THORNBURGH: -- the, you know, 3 biocompatibility of this mesh. the antioxidant additives, Santonox R, which -- do 4 BY MR. THORNBURGH: you have an understanding that Santonox R is used to 5 So according to this document, you'd prevent oxidation during the manufacturing of the Prolene meshes? 6 have to agree it's based on this document and based б 7 on what you have seen, the ten-year study, that 7 I've answered all that I can answer showed surface degradation in the Prolene sutures 8 about this line of questioning. A polymer that were tested had greater antioxidants to protect 9 chemist -- need to be discussing these specifics against oxidation than current TVT? 10 with a polymer chemist or an engineer. 10 11 MR. THOMAS: Object to the form of 11 Well, you rely on a lot of studies 12 that were conducted prior to -- for your -- for 12 the question. 13 BY MR. THORNBURGH: your -- the studies related to degradation that 14 Q. That's what this document would predate 1991, which show that in 1991, there was a suggest, right? 15 15 reduction of antioxidants in the Prolene suture, MR. THOMAS: Excuse me. You've asked 16 right? 16 17 about three questions and haven't let him answer any 17 MR. THOMAS: Object to the form of 18 of them. Do you want to start over again? Which 18 the question; scope. question do you want him to answer? 19 19 THE WITNESS: That's correct, and at 20 Excuse me. Stop. Just --20 the same time, there are plenty of studies conducted 21 21 BY MR. THORNBURGH: after 1991 that address these same endpoints. 22 According to this document, the 22 MR. THORNBURGH: Move to strike 23 23 sutures that were tested by Dan Burkley in the everything after, that's correct. ten-year data would have more antioxidants than the 24 24 We've got to change the tape. 25 antioxidants in the TVT, correct? THE VIDEOGRAPHER: We're now going

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	Page 495		Page 497
1	off the video record. It's now 2:40.	1	the question.
2	This concludes Volume 2, Tape	2	THE WITNESS: That's what it says.
	Number 3 of the videotape deposition of Dr.	3	BY MR. THORNBURGH:
4	Thomas A. Barbolt.	4	Q. And we know from your prior testimony
5	(Short break.)	5	that the additives, including Santonox, Lubrol,
6	THE VIDEOGRAPHER: We're back on the	6	DLTDP, those additives can bloom to the surface of
7	video record. It's now 3:00 p.m.	7	the polypropylene sutures and meshes, correct?
8	This begins Tape Number 4, Volume 2	8	A. Yes, they can.
9	of the videotaped deposition of Dr. Thomas A.	9	Q. And can leach out of the out of
10	Barbolt.	10	the fibers in vivo, correct?
11	BY MR. THORNBURGH:	11	A. Yes. I think that's likely.
12	Q. Okay. Dr. Barbolt, before we went	12	Q. It says calcium stearate is another
13	off the record, we were talking about a change, a	13	additive; DLTDP, an antioxidant to improve long-term
14	reduction in the levels of Santonox after 1991. Do	14	storage of the resin.
15	you remember that?	15	Do you see that?
16	A. Yes.	16	A. Yes.
17	Q. And this document goes on to say that	17	Q. So this is an antioxidant used,
18	the Santonox is an antioxidant that protects the	18	according to this document, used to prevent
	resin from thermal oxidation during extrusion.	19	oxidation during the storage of the product,
20	According to this document, the	20	correct?
21	Santonox is only there to protect against oxidation	21	MR. THOMAS: Object to the form of
22	ex vivo, right?	22	the question.
23	MR. THOMAS: Object to the form of	23	THE WITNESS: I see that.
24	the question.	24	BY MR. THORNBURGH:
25	THE WITNESS: I really can't address	25	Q. Again, Santonox R is an antioxidant
	Page 496		Page 498
1	the intention of the inclusion of the Santonox R as	1	to promote stability during compounding and
2	an antioxidant, but, clearly, as it's stated, it	2	extrusion, correct?
3	helps prevent oxidation during extrusion from heat,	3	MR. THOMAS: Object to the form of
4	but it may have other purposes to protect against	4	the question.
5	any other oxidation. Since it's a free radical	5	THE WITNESS: Yes. That's what it
6	scavenger, that would be its function.	6	Says.
7	But short of that, this would be for	7	BY MR. THORNBURGH:
8	a polymer engineer to address more specifically.	8	Q. And Procol LA is a lubricant to help
9 10	BY MR. THORNBURGH: Q. Well, extrusion happens outside the	9	reduce tissue drag and promote tissue passage. Do you see that?
11	Q. Well, extrusion happens outside the body, right?	11	A. Yes.
12	MR. THOMAS: Object to the form of	12	MR. THOMAS: Object to the form of
13	the question.	13	the question.
14	BY MR. THORNBURGH:	14	BY MR. THORNBURGH:
15	Q. During the manufacturing process?	15	Q. And the SCP pigment is a colorant to
16	MR. THOMAS: Object to the form of	16	enhance visibility.
17	the question.	17	Do you see that?
18		18	MR. THOMAS: Same objection.
19	THE WITNESS: EXTRUSION OCCURS during		
エフ	THE WITNESS: Extrusion occurs during the manufacturing process.	19	THE WITNESS: Yes.
20	the manufacturing process. BY MR. THORNBURGH:	19 20	THE WITNESS: Yes. BY MR. THORNBURGH:
	the manufacturing process.		BY MR. THORNBURGH:
20	the manufacturing process. BY MR. THORNBURGH:	20	BY MR. THORNBURGH:
20 21	the manufacturing process. BY MR. THORNBURGH: Q. So according to this document, the	20 21	BY MR. THORNBURGH: Q. So according to this document, the
20 21 22	the manufacturing process. BY MR. THORNBURGH: Q. So according to this document, the Santonox is an antioxidant that protects the resin	20 21 22	BY MR. THORNBURGH: Q. So according to this document, the DLTDP and the Santonox are antioxidants used to

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Page 499 Page 501 1 MR. THOMAS: Object to the form of non-cytotoxic polypropylene mesh, Prolene. 2 The tissue reaction in TVT mesh was the question. 3 THE WITNESS: That's what's stated in 3 characterized generally by mild, chronic 4 this document. 4 inflammation during the 28-day study, which was 5 BY MR. THORNBURGH: 5 comparable to the tissue reaction observed for 6 6 So let's go back to Exhibit T-2132. Q. Prolene mesh. 7 7 Again, this document is the mechanism Do you see that? 8 of cytotoxicity for TVT polypropylene mesh that we 8 A. Yes. 9 9 were discussing, which you drafted sometime while Q. That was a short-term study, correct? you were employed with Ethicon, correct? 10 28-day study. It would be considered 10 A. 11 11 A. Yes. short term. 12 Q. And we discussed how Santonox R 12 Q. And that was a study that looked at 13 13 tested severely cytotoxic at 3 milligrams per inflammatory -- or tissue response differences 14 milliliter, but non-cytotoxic at 2 milligrams per 14 between two mesh devices, both of which contained 15 milliliter, right? 15 blooming and leaching additives, including Procol, 16 MR. THOMAS: Object to form. 16 correct? 17 It's .2 milligrams per milliliter. 17 Α. Yes, but likely to different extents. 18 18 MR. THORNBURGH: .2 milligrams per Q. You're comparing apples to apples --19 milliliter. Thank you, Counsel. 19 apples to apples in this experiment, weren't you? 20 THE WITNESS: Yes, that's correct. 20 Apples to apples? 21 21 BY MR. THORNBURGH: MR. THOMAS: Object to the form of 22 22 And you go on to say that the Procol, the question. 2.3 BY MR. THORNBURGH: 23 which is the compound here, is the polyoxyethylene 24 lauryl. 24 Q. Yeah. 25 25 A. Do you see that? I don't understand. Page 500 Page 502 1 A. Yes. 1 Well, we've already -- you've already 2 established, and these documents establish and your Q. And the Procol was tested at 3.5 milligrams per milliliter and resulted in severe 3 testing established, that Procol, which was 4 cytotoxicity. contained in both of these products, was severely cytotoxic, even at very low levels, right? Severe -- so then, you ran another 6 б Yes, as we discuss in the paragraph test, reducing the volume of Procol, which again 7 7 tested severely cytotoxic, correct? at the top. 8 8 So you are testing two mesh products, A. Q. 9 Q. And then you reduced it yet again. 9 both of which contained a severely cytotoxic And the third test further confirmed the severe additive, to compare the difference in tissue 10 10 cytotoxic potential of Procol, correct? 11 reaction, correct? 11 12 12 A. Yes. 13 Q. And Procol is an additive that can 13 MR. THOMAS: Object to the form of 14 bloom to the surface during the manufacturing 14 the question. 15 process and leach out while implanted in a woman's 15 BY MR. THORNBURGH: 16 body, correct? 16 Now, one of the differences I assume 17 17 that you'll testify to is -- well, strike that. MR. THOMAS: Object to the form of 18 the question. 18 In summary, this data suggests that 19 THE WITNESS: Yes. 19 the probable mechanism of cytotoxicity of the 20 BY MR. THORNBURGH: 20 polypropylene mesh from the TVT devices is the 21 It says: To evaluate the presence of Procol LA-10, a potent non-ionic 22 significance of the cytotoxicity in a clinically 22 surfactant, with the ability to disrupt cell relevant in vivo system, an intramuscular 23 membranes and cause cell death in in vitro systems. implantation study was conducted in rats using Right? 24 cytotoxic polypropylene mesh from the TVT device and 25 That's correct.

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Page 503 Page 505 1 1 The increased cytotoxicity of Do you recall writing a Q. polypropylene suture -- and this is a question I biocompatibility assessment where you say 3 specifically that the -- what you'd expect to see in have for you. 4 The increased cytotoxicity of vivo if TVT was cytotoxic would be delayed or wound 5 polypropylene suture after autoclaving can be 5 healing defects or ulcerations? attributed to the increased amount of Procol LA in 6 I don't recall that specifically. A. 7 7 aqueous extracts. Thus, any treatment in Certainly, the adverse impact in wound healing. And 8 polypropylene mesh which would result in more or I guess if it's severe enough, it might cause 9 9 less of Procol LA-10 available for extraction would ulceration of overlying tissue, but I don't recall be expected to result in greater or lesser 10 that specifically. 10 11 11 cytotoxicity respectively. O. You would agree that based on the 12 Do you know if the polypropylene in 12 evidence, TVT, the Prolene in TVT, showed evidence 13 13 TVT is autoclaved? of cytotoxicity --14 14 A. No. Sterilized by ethylene oxide. MR. THOMAS: Object to the form of 15 Q. Okay. But the issue with autoclaving 15 the question. was the additional heat that is applied to sterilize 16 BY MR. THORNBURGH: 16 17 17 the mesh, right? -- at least in vitro? 18 18 A. The suture and -- yes, that's A. Yes. It showed evidence of 19 correct. 19 cytotoxicity in vitro. 20 20 And nowhere in the IFU are those Q. Which can cause blooming of these 21 findings disclosed to physicians, correct? 21 additives at the surface of the polypropylene. Is 22 that correct? Yes. And that's because there's no 22 23 A. 2.3 translation to increase tissue reaction or adverse Yes. That's the hypothesis. 24 Q. Now, what we know from your prior impact in wound healing. 25 testimony is that the TVT device undergoes the heat 25 Have you seen the studies that show Q. Page 504 Page 506 shrink tubing, which also can cause blooming of that the Prolene mesh can cause chronic wound antioxidants like -- or the additives like Procol to 2 healing problems? 2 3 the surface of the TVT fibers, correct? 3 MR. THOMAS: Object to the form of 4 A. Yes, that's correct. 4 the question. 5 And if the Procol blooms to the 5 THE WITNESS: No. I'd have to see surface during the manufacturing process, it can б the specific reports that you're talking about. б 7 7 increase the risk of cytotoxicity, correct? BY MR. THORNBURGH: 8 MR. THOMAS: Object to the form of 8 I am asking you: Do you recall 9 the question. 9 seeing any studies as you sit here -- did you review THE WITNESS: It can increase the 10 any studies before you came in here today that 10 showed that the Prolene -- that the polypropylene risk of cytotoxicity in vitro. However, all of the 11 11 in vivo implantation studies suggest that that's not 12 meshes can lead to chronic wound healing problems? the case; that the substance that might cause severe 13 MR. THOMAS: Object to the form of 13 14 in vitro cytotoxicity is not making a contribution 14 the question. 15 to increased tissue reaction in vivo. 15 THE WITNESS: No. BY MR. THORNBURGH: 16 BY MR. THORNBURGH: 16 Well, some of the things that -- some 17 Did you review any studies before you 17 18 of the symptoms that we would see if polypropylene 18 came here today that show that the Prolene in TVT in TVT is cytotoxic would be increased tissue 19 can cause erosions and extrusions through the 19 20 reaction, wound healing defects, and ulcerations, 20 vaginal wall? 21 correct? 21 MR. THOMAS: Object to the form of 22 A. I think certainly increased tissue 22 the question. 23 reaction and adverse impact in wound healing. The 23 THE WITNESS: No. And that would be 24 ulceration question, it kind of depends. I 24 in the clinical area, and my responsibility here is generalized by saying that. to address preclinical questions.

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Page 507 Page 509 BY MR. THORNBURGH: 1 THE WITNESS: Okay. 1 2 Did you look at any -- any of the BY MR. THORNBURGH: 3 3 explant reports that Ethicon received that showed And it will relate preclinically. that women who had mesh devices explanted, also, 4 A. Okay. Fine. 5 some of those women had ulcerations? 5 We'll talk about it and refresh in Q. 6 MR. THOMAS: Object to the form of 6 the preclinical context. 7 7 Okay. Fine. the question. A. 8 THE WITNESS: There would be a 8 Q. Now, this is a document that 9 9 clinical explant, and I have not reviewed any of discusses problems with particle loss that were that information. being experienced -- were experienced by Ethicon 10 BY MR. THORNBURGH: 11 regarding its TVT products, correct? 11 12 12 MR. THOMAS: Object to the form of O. You have also been designated as the 30(b)(6) witness to discuss the specifics of all 13 13 the question. testing related to TVT products during the design, 14 14 THE WITNESS: I'm sorry. I was kind 15 development stages, including but not limited to 15 of reading through here, and I see that I have 16 porosity testing, particle loss, degradation, and 16 looked at it before. 17 leaching. We'll shorten that up. 17 Could you please repeat that You have also been designated as the 18 18 question? 19 Ethicon person who will testify regarding all 19 BY MR. THORNBURGH: 20 testing related to the TVT products and particle 20 Yeah. This is an e-mail from Dan Q. 21 loss. Correct? 21 Smith to Janice Burns which discusses problems of 22 particle loss that were being seen by doctors in the A. Yes, that's correct. 2.3 MR. THORNBURGH: Off the record. 23 field who were using the TVT product, right? 24 THE VIDEOGRAPHER: Off the video 24 MR. THOMAS: Object to the form of 25 record, 3:18. 25 the question. Page 508 Page 510 1 (Short break.) 1 THE WITNESS: Yes. That's what it 2 THE VIDEOGRAPHER: Back on the video looks like. 3 record, 3:24. 3 BY MR. THORNBURGH: 4 BY MR. THORNBURGH: 4 And in that context, Dan Smith says: 5 Doctor, I want to mark as -- give me This is not going away any time soon, and Q. competition will have a field day. Major damage б one second. б 7 7 control offensive needs to start to educate reps and There we go. I am going to mark as Exhibit Number 2255 an e-mail dated February 27, 8 8 surgeons upfront they -- that they will see blue 9 2004. shit, and it is okay. This is why I wanted to launch TVT-O in clear. 10 (Document marked for identification 10 as Exhibit T-2255.) 11 Do you see that? 11 12 BY MR. THORNBURGH: 12 Yes. A. 13 This is an e-mail from Dan Smith to a 13 And when you worked for -- as 14 number of -- or to Janice Burns dated February 27, 14 Ethicon, you recognize that there is -- at least 2004, discussing issues with TVT and particle loss. 15 during the mechanical cut days of TVT mesh, there 15 Right? was a problem with particles falling away from the 16 MR. THOMAS: Object to the form of 17 17 mesh, right? 18 the question. 18 MR. THOMAS: Object to the form of THE WITNESS: I've not seen this 19 19 the question; scope. 20 memo, and I am not sure that it relates to the 20 THE WITNESS: Yes. 21 biocompatibility or particle loss in a preclinical BY MR. THORNBURGH: arena. I have to read through here --22 In fact, that same month -- I've 22 Q. 23 MR. THOMAS: I think they showed it 23 handed you what's been marked as Exhibit 24 to you at your last deposition. 24 Number 2256. 25 25 MR. THORNBURGH: Yeah. (Document marked for identification

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Page 511 Page 513 BY MR. THORNBURGH: as Exhibit T-2256.) 2 MR. THOMAS: May I have one, please? 2 What's been marked as Exhibit 3 3 BY MR. THORNBURGH: Number 2257 is a document or a fax that was received 4 That same year, in November of 2004, 4 by Basso Sibylle to David Menneret, who said: 5 Ethicon received an e-mail concerning complaints 5 Attached is Dr. Eberhard's letter regarding TVT blue from Dr. Eberhard. tape. 7 7 It says: Dear all, please see Do you see that? 8 attached below a letter with pictures of 8 Yes. A. 9 9 competitor's device and its translation from Dr. (Document marked for identification Eberhard, an important customer in Switzerland, 10 as Exhibit T-2258.) 10 regarding mesh fraying. Regarding the mesh frayed 11 BY MR. THORNBURGH: 11 12 complaints, decision is not open corrective 12 I've marked as Exhibit Number 2258 O. 13 13 action -- a decision to not open corrective action the translated letter from Dr. Eberhard, who writes: 14 is based on the following memo. Could you please 14 Dear Emilie, Business Unit Manager Gynecare 15 give feedback? 15 Switzerland. Please find attached a TVT tape which 16 16 was used as a demo unit for patients before they had So this is an e-mail regarding Dr. Eberhard, who had written a letter to Ethicon 17 their operation. Already at the operation, it is 18 embarrassing to see how the tape is crumbling. It 18 regarding problems with the mesh devices, right? 19 MR. THOMAS: Object to the form of 19 gets worse if there is stretch on the tape. 20 20 I can't understand that no one will the question; scope. 21 THE WITNESS: Yes. It looks that to 21 solve the problem for such a long time. At least as 22 22 be the case. the tape has becoming blue, everyone has realized 2.3 BY MR. THORNBURGH: 23 that the quality of the tape is terrible. A tape 24 And David Menneret on November 9th -has to be weaved and should not crumble. Please try 25 of November 12th of 2004 wrote that: We already one and you will see that the tape is crumbling. Page 512 Page 514 1 received similar complaints. This kind of issue is Did I read that correctly? 2 usually attributed to over-tensioning of the tape 2 MR. THOMAS: Object to the form; 3 during the procedure. Fraying is inherent in the 3 scope. product based on the mesh construction. When any 4 THE WITNESS: Yes. amount of tension is applied to the mesh, fraying 5 (Document marked for identification as Exhibit T-2259.) occurs. Stretching of the mesh increases the б б 7 7 probability of fraying. BY MR. THORNBURGH: 8 Do you see that there? 8 Marked as Exhibit Number 2259 a 9 MR. THOMAS: Object to the form of 9 compilation of e-mails --10 MR. THOMAS: May I have one, please? 10 the question; scope. 11 THE WITNESS: Yes. 11 MR. THORNBURGH: I'm sorry, Counsel. BY MR. THORNBURGH: 12 12 BY MR. THORNBURGH: 13 I am going to put it in the scope of 13 -- a string of e-mails in which 14 the deposition. So according to David Menneret, one 14 Charlotte Owens was one of the recipients and 15 of the problems with fraying and particle loss was 15 authors of the e-mails. from tensioning of the mesh and specifically 16 Do you know who Charlotte Owens is? 16 17 tensioning of the TVT tape or the tape that was I think we overlapped a little bit. 17 18 being used by Ethicon, correct? 18 Obviously, she is a medical director of Gynecare. MR. THOMAS: Same objection. 19 19 So she was in charge, the director of 20 THE WITNESS: Yes. I think that's 20 the medical affairs part of Ethicon, right? 21 Yes, for Gynecare. 21 what they're referring to. A. 22 (Whereupon, a discussion was held off 22 For Gynecare. Q. 23 the record.) 23 And she received, according to this document, an e-mail from Dan Smith, who appears to 24 (Document marked for identification 25 as Exhibit T-2257.) have included an e-mail or an excerpt from something

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Page 515 Page 517 authored by Steve Bell of Gynecare. the question. 1 2 It says: Dear all, as more and more 2 BY MR. THORNBURGH: 3 customers now move to TVT blue and TVT-O with blue Yes, Doctor? Q. 4 mesh, you may sometimes hear, I can see small blue 4 A. Yes. 5 pieces come off the mesh. What's wrong? 5 Q. This doesn't -- this summary doesn't 6 say remind physicians that Prolene mesh is The key points, it says, number two, 7 7 susceptible to surface degradation, does it? the same -- number one, Gynecare blue TVT mesh and 8 Gynecare clear TVT mesh are exactly the same. 8 I don't know that I should be even 9 9 Number two, the same number of commenting on this exchange between a marketing particles came off the clear mesh when it was 10 person and the field. 10 11 11 stretched. Q. Well ---12 12 Do you see where it says "when it was A. First, he's not a scientist. Second, 13 13 stretched"? Do you see that? I am not sure what it's got to do with the 14 A. Yes. 14 preclinical data that we brought here to talk about. 15 Q. 15 I am going to put it all into Okay. It's just that you see them 16 against the tissue and skin more when they are blue. context. I assure you. 16 Okay. This is no different to what has happened in the 17 17 A. 18 But it says -- it doesn't say remind 18 past seven years with TVT. 19 Reassure your doctors that this is 19 physicians who are purchasing these permanent 20 part of the success of TVT. The way we have cut the 20 implants which are going to be put into -- in and 21 mesh makes the edges softer, and we feel that this 21 around the vaginal area of the woman's body, that 22 has been a crucial success factor in TVT. Reassure the surface area or the surface layer of the Prolene that Prolene has proven to be inert. 23 in the TVT is susceptible to surface cracking or 23 24 Do you see that? "Proven to be surface degradation, right? 25 inert." Right? 25 MR. THOMAS: Object to the form of Page 516 Page 518 1 A. Yes. I see that. the question. Scope. 2 2 THE WITNESS: I want to make a Q. In summary, be proactive. The 3 competition will try to target this, especially 3 distinction between particles shed from the mesh, 4 Bard, as they have a sealed edge tape, and remind 4 which I consider a macroparticle, and the kind of your customers it is the same as clear. It is microparticles that you're alluding might shed from 6 proven safe implant. In the blue format over б or as a result of some sort of surface cracking 7 100,000 have been implanted worldwide. Remind them 7 observed on the Prolene fiber. Two different that the benefits -- of the benefits of blue mesh. 8 issues. Remind them it is inert Prolene with over 25 years 9 BY MR. THORNBURGH: of health. Remind them our wealth of clinical data 10 10 Both --11 with ultra low complication rates. 11 MR. THOMAS: Are you finished? 12 12 THE WITNESS: Yeah. Do you see that? 13 A. Yes. I can read it. 13 MR. THOMAS: Sorry. 14 Okay. So number one is -- there's 14 BY MR. THORNBURGH: 15 particle loss being seen when the tape is stretched. 15 Both of which, by themselves, can 16 Do you see that? 16 elicit a -- an inflammatory response. 17 MR. THOMAS: Object to the form of 17 MR. THOMAS: Object to the form of 18 the question; scope. 18 the question. 19 19 THE WITNESS: Yes, I see it. BY MR. THORNBURGH: 20 BY MR. THORNBURGH: 20 In fact, nanoparticles or 21 21 Okay. And, number two, we know from microparticles will excite macrophages more than 22 what we've seen in the internal studies by Ethicon 22 macroparticles will. that the Prolene in the TVT mesh is susceptible to 23 MR. THOMAS: Which question do you 24 surface degradation, correct? 24 want him to answer? 25 MR. THOMAS: Object to the form of 25 BY MR. THORNBURGH:

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Page 519 Page 521 Q. 1 1 Correct? It's not the same implant condition Q. 2 MR. THOMAS: Which question do you that is occurring in women who are having these 3 want him to answer? You posed two of them. implants put in their bodies for the rest of their 4 MR. THORNBURGH: Both. 4 lives --5 5 MR. THOMAS: One at a time. MR. THOMAS: Object to the form of 6 MR. THORNBURGH: My last one first. 6 the question. 7 7 THE WITNESS: So the first part, the BY MR. THORNBURGH: 8 fragments that we've talked about that have been 8 Q. -- right? 9 9 observed alongside the suture and in what I call MR. THOMAS: Scope. 10 macroparticles have a tissue reaction to them very 10 THE WITNESS: I don't know all the 11 11 similar to the polypropylene fiber. parameters of that condition that you make reference 12 And the second question in terms of 12 to, okay, because I suspect that each patient has 13 13 these microparticles that I make reference to that different issues. 14 14 you allude would come off the surface as a result of And this study was an attempt to make 15 surface cracking, there's been no evidence in any of 15 the implantation procedure very consistent so that 16 the 49 documents that I've brought today that we could determine whether or not there is 16 17 there's an increase in tissue reaction over time. stretching of the tape or deposition of particles in 18 18 And, in fact, in many studies, there's a diminution the surrounding tissue. 19 of the tissue reaction over time. So there's no 19 BY MR. THORNBURGH: 20 20 You didn't answer my question evidence to support that second piece. Q. 21 21 BY MR. THORNBURGH: completely. 22 22 O. The truth is the testing that you and It's not the same implant condition 23 Ethicon were doing preclinically was really 23 that is occurring in women who are having these marketing studies. They were studies to -- that implants put into their bodies for the rest of their were being conducted because of the threat from 25 lives. Page 520 Page 522 1 competitors like Bard. 1 MR. THOMAS: Object to the form of 2 MR. THOMAS: Object to the form of the question; scope. And, also, he did answer your 3 the question; scope. auestion. 4 THE WITNESS: Absolutely not. The 4 BY MR. THORNBURGH: preclinical studies conducted by Ethicon were either 5 Well, number one, rabbits are 5 for regulatory submission or for internal б quadrupeds, not bipedal, right? 6 7 7 information to advance product development. Well, I thought we were talking about 8 BY MR. THORNBURGH: 8 the conditions of implantation, and it would have 9 When you did rabbit studies that 9 nothing to do with the number of legs. Q. looked at particle loss in rabbits, the tape that 10 Well, we're talking about -- we're 10 was being implanted in the rabbits was not 11 talking about the condition, the real human 11 12 undergoing the same type of stresses and strains condition, compared to the animal condition where that the tape undergoes in the human environment or 13 you conducted these studies. 13 14 the human condition when the device is being 14 MR. THOMAS: He's not a clinical guy. 15 implanted, correct? 15 MR. THORNBURGH: Number one -- I MR. THOMAS: Object to the form of 16 think he can say pretty easily that rabbits are 16 17 17 the question; scope. bipedal -- or quadrupeds, not bipeds. 18 THE WITNESS: As I recall in that 18 BY MR. THORNBURGH: 19 study -- and we could make reference to it, and I Right? 19 Q. probably should go to it -- that they implanted the 20 I said I don't know all the 20 A. mesh in a manner that the mesh might be implanted in 21 conditions in the clinical situation that you're patients; that is, insertion, passage through 22 alluding to and whether or not they would compare 22 muscle, which would offer up some tension, and then 23 with the passage of mesh through skeletal muscle of 24 rabbit. implantation. 25 BY MR. THORNBURGH: 25 Your rat study, which has previously

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Page 523 Page 525 musculature. been marked as T-2133, ETH.MESH.05316775 --2 MR. THOMAS: Which one are we talking 2 Okay. And how much mesh is implanted 3 3 in women during the implant process? about, Dan? 4 4 MR. THORNBURGH: Sorry. MR. THOMAS: Object to the form of 5 5 MR. THOMAS: Which study? the question; scope. 6 6 MR. THORNBURGH: Yeah. The THE WITNESS: I don't know that 7 7 histological evaluation and comparison of mechanical number. That's a clinical issue, and it would 8 pullout strength of Prolene and Prolene Soft mesh in 8 depend on which TVT product you're talking about. 9 9 a rabbit model. BY MR. THORNBURGH: 10 Let's go ahead and mark it as an 10 Well, the more mesh, the more 11 particles there are to flake off of the mesh device, 11 exhibit. 12 12 It's already been marked, Exhibit right? Number 2133. Sorry. 2133. It was marked at a 13 MR. THOMAS: Object to the form of 13 14 the question. 14 prior deposition. 15 MR. THOMAS: Oh, okay. 15 THE WITNESS: I don't know that for 16 16 Do you have another one? certain. 17 BY MR. THORNBURGH: MR. THORNBURGH: Yeah, I do. Sorry. 18 I think I left the extra copy -- oh, found it. 18 Q. You don't know that? 19 2133. 19 A. 20 BY MR. THORNBURGH: 20 Did you look at the Pariente study 21 before you came here today? 21 Now, Ethicon was concerned about 22 22 the -- what the competition would say about the TVT A. No. products as a result of the particles that were 23 Do you recall discussing the Pariente 23 Q. being seen with the TVT blue, correct? 24 study during your deposition last time? 25 MR. THOMAS: Object to the form of 25 A. The name sounds familiar. Page 524 Page 526 the question; scope. 1 Do you recall that in the Pariente 2 THE WITNESS: Yeah. And I guess I study, it was found that 8.5 percent of the 3 can't really address what Ethicon was thinking and particles in the TVT mesh fell away from the TVT why they did stuff, only to -- insofar as it 4 product? reflects the documents that we brought here today to MR. THOMAS: Object to the form of talk about biocompatibility or any preclinical б 6 the question; scope. 7 7 THE WITNESS: I don't recall that studies. 8 BY MR. THORNBURGH: 8 information. 9 So you conducted a 14-day rabbit 9 BY MR. THORNBURGH: Q. 10 Did any of your studies try to mimic 10 study, right? the stresses and strains that were used in the 11 Ethicon conducted such a study. 11 A. Pariente study during the implantation of the mesh 12 And women who have these devices 13 implanted in their bodies are -- the intention is 13 in rabbits, and in this case, in rabbits for 14 that these implants will remain in their bodies for 14 14 days? the rest of the woman's life, correct? 15 MR. THOMAS: Object to the form of 15 A. 16 the question; scope. 16 Now, how much mesh -- what was the 17 Do you have one to show him? 17 Q. 18 size of the mesh implanted in the rabbits? 18 THE WITNESS: Was it a clinical study The mesh was -- the TVT tape width, or a preclinical study? 19 19 20 about 10 millimeters. That's what was implanted. 20 MR. THOMAS: That's why I want you to 21 And samples of Prolene Soft mesh and ultrasonically see it. cut mesh were done in a very similar way. 22 MR. THORNBURGH: It was an ex vivo 22 23 And as I look on Page 23 study. 24 ETH.MESH.05316780, the intention was to leave 3 24 THE WITNESS: It could be ex vivo 25 from animals or humans. 25 centimeters of that mesh within the epaxial

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Page 527 Page 529 BY MR. THORNBURGH: 1 1 Q. Well, then, you didn't consider the 2 Do you know sitting here today level of force used when implanting a TVT-Retropubic 3 whether the studies that you did were -- whether or in women to try to mimic the same loads being 4 not you used the Pariente study to determine 4 applied to the one and-a-half inch piece of mesh 5 particle loss in any of the studies that you did? 5 that you're implanting in these rabbits, did you? 6 MR. THOMAS: Object to the form of 6 I can't speak to anything that was 7 7 the question; scope. done in the clinical environment. 8 THE WITNESS: It's not indicated in 8 Did you ask anybody from the clinical 9 9 the study report, any reference to the Pariente environment: Hey, you know what? We want to try 10 to, in the preclinical environment, to test this study. 11 BY MR. THORNBURGH: issue. We want to determine the amount of force or 12 12 loads that are being applied during the implantation Q. What loads were used when implanting of a larger piece of mesh in women so that we can 13 the 3-centimeter by 1-centimeter samples in these 13 14 rabbits? 14 mimic that condition in the preclinical studies that 15 MR. THOMAS: Object to the form of 15 we're doing with one and-a-half piece of mesh? 16 16 the question. That was not done --MR. THOMAS: Object to the form of 17 17 THE WITNESS: As indicated in the 18 study report, the mesh was drawn through the 18 the question. 19 epitaxial musculature, and whatever forces that 19 BY MR. THORNBURGH: 20 would offer the mesh, that's what happened. 20 You did not. Did you have any 21 BY MR. THORNBURGH: 21 discussions with anybody in the clinical arena to 22 22 And can you hold up for the ladies determine the implant conditions in women to try to 23 mimic those implant conditions in the animals that 23 and gentlemen of the jury approximately 3 24 centimeters? you were testing this mesh in? 25 25 That's not indicated in this report. A. Maybe an inch and-a-half. A. Page 528 Page 530 So your study in rabbits was about an Those discussions may have taken place. inch and-a-half piece of mesh that was implanted in 2 Did you do that? Did you try -- did 3 the muscle of the rabbit for 14 days max, right? 3 you understand or try to understand the amount of 4 A. That's correct. force or loads in any of the studies that you did 5 Did you measure the force by Newtons in -- that were -- that were needed for implantation or the load by Newtons that would be used or was in women so that you could mimic the same implant б б 7 used during the implantation process to determine 7 condition in your preclinical studies? 8 whether or not it would mimic the implantation 8 MR. THOMAS: Object to the form of 9 conditions in human women? 9 the question. 10 THE WITNESS: Again, you're talking 10 No assessments of force required to implant the mesh samples was recorded, only the 11 about data that would be collected in a clinical 11 12 explant tensions. environment, and I am not here to address that other than the preclinical data that we brought and 13 Do you know what forces are used 13 14 during the implantation process in women? anything that's relevant to it. MR. THOMAS: Object to the form of 15 BY MR. THORNBURGH: 15 16 Did you discuss with anybody for any 16 the question. Scope. Q. THE WITNESS: It is a clinical 17 of the preclinical studies or before you walked in 17 18 question. 18 here today what the implant conditions are like in 19 BY MR. THORNBURGH: terms of a force required to implant the stretching 20 Well, isn't that -- isn't that 20 that's done during the implant procedure so that you clinical information important when you're trying to 21 could gain a better understanding of your determine particle loss in rabbits? 22 preclinical studies? 22 23 This preclinical study was an attempt 23 MR. THOMAS: Object to the form of to simulate implantation in patients. And it is 24

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THE WITNESS: That's the kind of

25

the question.

24

what it is.

25

Page 531 Page 533 information that would be in the clinical arena, and before and after soft procedure, and values range 2 from 0 to 8.5 percent of initial weight. that's not part of what I am here to discuss. 3 3 BY MR. THORNBURGH: Did you -- in any of your studies, 4 Q. But you didn't discuss with anybody 4 did you weigh the sample pre and post procedure? 5 in the clinical arena whether or not the preclinical 5 studies that you're trying to rely on now were done 6 MR. THOMAS: Pre-implant? 7 7 in a condition that would mimic the human implant BY MR. THORNBURGH: 8 condition? 8 Pre-implant and post explant. 9 9 MR. THOMAS: Object to the form of No. That would not be practical, 10 because there would be tissue adherent to the mesh, 10 the question. 11 and it would alter its weight. 11 THE WITNESS: I think I've answered 12 that three times, and the same answer I'll give now, 12 So you didn't look at the weight to and that is this information would be collected in a 13 determine particle loss, did you? 14 No. But we looked at something more 14 clinical environment and is not part of what I am 15 here to discuss. 15 important than that in the study that we discussed BY MR. THORNBURGH: 16 earlier, and that is whether or not particles were 16 17 17 observed in the immediate vicinity of the implant. Let's go ahead and mark as 18 Exhibit 2260 the Pariente study. 18 Q. You didn't look at weight, did you? (Document marked for identification 19 19 A. 20 as Exhibit T-2260.) 20 You didn't determine the percent of 21 MR. THORNBURGH: Dave, I have a copy 21 particle loss in any of your studies, did you? 22 As I pointed out -for you, and I just don't have -- it's not stapled. 23 23 MR. THOMAS: That's fine. Thank you. It's a yes or no question. Q. 24 BY MR. THORNBURGH: 24 A. As I pointed out, weighing a mesh 25 You've seen this study before, after implantation would not be useful, because Page 532 Page 534 haven't you? there would be additional weight of tissue adherent 1 2 2 A. I think I have, but it doesn't look to it. 3 so familiar. The name does seem familiar, but I'd 3 Q. It could dissolve the tissue, right? have to read through it to see what happened here. 4 MR. THOMAS: Object to the form of 5 Do you want to take a moment and look 5 Q. the question. at it? THE WITNESS: That would be a б б 7 7 possibility. Α. Sure. 8 Okay. This looks like an in vitro 8 BY MR. THORNBURGH: 9 9 So you could have weighed it after study. dissolution or dissolving -- desiccation of the 10 Q. Did you look at this study before you 10 came in here today? 11 tissue, right? 11 12 A. 12 That's possible. That could 13 Q. You don't recall looking at the study 13 introduce other things that you would have to control for, but, clearly, there's no end to the 14 with me during your prior deposition? Again, I think the name rings a bell, 15 number of studies that could be conducted. 15 A. but I've looked at a lot of studies. But you didn't do that study, did 16 16 Q. you? Okay. Well, in the Pariente study, 17 17 18 the investigators were looking at -- as their 18 A. No. endpoint or one of their endpoints, particle loss, 19 And you didn't determine the 19 20 correct? 20 percentage of particle loss, correct? 21 21 MR. THOMAS: Object to the form of A. Yes. 22 Yes, I recall the study now. This 22 the question. 23 one we discussed during the last deposition. 23 THE WITNESS: That's correct. And it says here: To evaluate the BY MR. THORNBURGH: 24 24 25 25 shedding of particles, each sample was weighed Q. The study goes on to say: During

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	Page 535		Page 537
1	surgical use, these articles are released in soft	1	it might be associated with.
2	tissue, and it is not possible to know where they	2	Q. During surgical use, these particles
3	go.	3	are released in soft tissue, and it is not possible
4	MR. THOMAS: There's no question	4	to know where they go.
5	pending.	5	That's what these authors write,
6	BY MR. THORNBURGH:	6	correct?
7	Q. Do you see that?	7	MR. THOMAS: Object to the form of
8	A. Yeah, I see it.	8	· ·
9		9	the question; scope.
10	Q. And that's true? When particles are	10	THE WITNESS: That is the opinion of these authors.
	released into soft tissue, they can migrate, can't	11	
11 12	they?	12	BY MR. THORNBURGH:
	MR. THOMAS: Object to the form of		Q. When these authors tested particle
13	the question.	13	loss, they found that the TVT lost the most
14	THE WITNESS: That's not very likely.	14	particles of all the things that were tested,
15	With any particles, any macroparticles that would be	15	correct?
16	adherent to the mesh or they might flake off the	16	MR. THOMAS: Object to the form of
17	mesh in vivo, they would reside in the immediate	17	the question; scope.
18	vicinity of the implant, and they would be	18	THE WITNESS: Under the conditions of
19	surrounded by connective tissue, just like each	19	their testing, that's the case.
20	element of the mesh.	20	BY MR. THORNBURGH:
21	BY MR. THORNBURGH:	21	Q. And they found that TVT lost
22	Q. When I get a splinter in my finger,	22	8.5 percent of the particles, right?
23	no matter how deep it is, my body's my body's	23	MR. THOMAS: Object to the form of
24	inflammatory response to that little tiny piece of	24	the question; scope.
25	splinter will push that splinter out of my body,	25	THE WITNESS: I think I think they
	Page 536		Page 538
1	migrate it from where it found itself initially	1	mean 8.5 percent of the weight was lost as
2	until it's outside of my body, won't it? That	2	particulates.
3	happens, doesn't it?	3	BY MR. THORNBURGH:
4	A. That can happen if it's close enough	4	Q. Yeah. I'm sorry. They found that
5	to the surface of your skin.	5	8.5 percent of the weight of the TVT sling was lost
6	Q. So migration of particles is possible	6	to particles, correct?
7	as a result of the inflammatory process that's	7	MR. THOMAS: Object to the form of
8	taking place in the human body, right?	8	the question; scope.
9	MR. THOMAS: Object to the form of	9	THE WITNESS: I think that's what
10	the question; scope.	10	they're saying.
11	THE WITNESS: Highly unlikely.	11	BY MR. THORNBURGH:
12	BY MR. THORNBURGH:	12	Q. Almost 10 percent of the TVT sling
13	Q. And that's based on what, sir?	13	was lost in their study through particle loss,
14	A. My experience looking at implanted	14	right?
15	materials and the experience from the Prolene suture	15	
	*		MR. THOMAS: Object to the form of
16	NDA, which calls out macroparticles of the suture,	16	the question; scope.
17	likely resulting from a swaging process of	17	THE WITNESS: Eight and-a-half
18	macroparticles that got adhered to the suture, and	18	percent.
19	they got implanted inadvertently with the suture.	19	BY MR. THORNBURGH:
20	And what's observed is that there's a	20	Q. Now, what loads were used to test TVT
21	tissue reaction around the filament of the suture	21	particle loss?
22	and then adjacent to it, the particle, or the very	22	MR. THOMAS: In what context, Dan?
23	similar reaction around it.	23	MR. THORNBURGH: In this study.
' 1 /1	Thorois no avidance that that	· ') /I	MD THOMAS. In which study?
24 25	There's no evidence that that particle will migrate away from the fiber from which	24 25	MR. THOMAS: In which study? MR. THORNBURGH: The Pariente study.

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Page 539 Page 541 MR. THOMAS: Thank you. lying adjacent to the implant. It would have the 1 BY MR. THORNBURGH: same kind of tissue reaction. It would be probably 3 Measured in K per Newton. Do you not discernable against the background of 4 know what that means? Peak load? 4 implantation of a mesh, even if it had no particles. 5 Well, I'm just looking at the text 5 (Document marked for identification where they talk about a soft procedure, and I'm 6 as Exhibit T-2261.) 6 7 7 BY MR. THORNBURGH: looking for the data that would be corresponding to 8 8 I marked as Exhibit Number 2261 a it. Q. 9 9 I think if you look here, maybe this side-by-side photograph of the -- a document that might help. includes a side-by-side photograph of mechanical cut 10 11 TVT mesh and laser cut TVT mesh. 11 Do you see Table 1? 12 It shows low deformation curves? 12 Have you seen this before? 13 13 A. No. It looks like they gave each A. I don't think so. 14 14 material a different load. Q. Do you see where it says side-by-side 15 Starting at? 15 relaxed after 50 percent elongation? Q. 16 TVT at .041 ranging to .012 for 16 MCM would mean mechanical cut mesh, Α. I-Stop. 17 17 right? 18 Q. Do you know how much load is used in 18 19 the implantation of the TVT? 19 MR. THOMAS: Object to the form of 20 I do not. 20 A. the question; scope. All of this is beyond -- excuse me. 21 Q. Do you know how much load you used 21 22 when you implanted the 1.5 by -- 3-centimeter by All of this is beyond what he's been designated for. 1-centimeter piece of mesh in the rabbits use study? 2.3 MR. THORNBURGH: No, it's not. 23 24 A. That was not measured. 24 BY MR. THORNBURGH: 25 You don't know sitting here today if 25 LCM is laser cut mesh? Do you see Q. Page 540 Page 542 the loads that you used would have mimicked the 1 that? loads used during the implantation of TVT in an 2 2 Do you see that? 3 actual woman, right? 3 A. I understand it's outside my area. 4 A. Well, as I mentioned four times 4 What -- what? No, it's not. I am Q. previously, that would be data coming from the 5 going to put it in context. 5 original -- the clinical arena, clinical б б What percentage of elongation was 7 environment, and it's not what I am here to address. 7 used in any of your studies to determine particle 8 And that information wasn't important 8 loss? for you when you designed the studies that looked at 9 Did you ever measure the elongation that was being applied during the implantation of 10 particle loss, was it? 10 11 MR. THOMAS: Object to the form of this device in any of the preclinical studies that 11 12 the question. 12 vou conducted? 13 THE WITNESS: Obviously, it was not 13 A. This might be the sixth time that 14 considered necessary to execute this protocol. 14 I've responded to that question, and it's the same. BY MR. THORNBURGH: 15 This is data that would be acquired 15 You would agree that if 8.5 percent 16 in the clinical environment and is not part of the 16 Q. of particles are being lost during the implant 17 preclinical database that I'm here to discuss. 17 18 procedure on the TVT mesh, that that would increase 18 O. No. I asked you a different 19 the inflammatory response. 19 question. My question was: In any of the 20 MR. THOMAS: Object to the form of preclinical studies that you did or that Ethicon did 21 21 to look at particle loss and tissue reaction, did the question; scope. THE WITNESS: Highly unlikely, given 22 22 you ever look at or record the percentage of the mass of material implanted as part of a tape. 23 23 elongation during the implantation in the animal Think about all of the monofilaments 24 24 study? 25 25 woven into a mesh, and think about some particulates A. Not that I'm aware of.

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Page 543 Page 545 1 Q. Do you see where it says degradation? contribution of a particle to the overall reaction 2 to the entire tape. MR. THOMAS: Where? What page are 3 3 Inflammatory cells would be released you on? 4 MR. THORNBURGH: I'm on the to attack that particle, to try to rid the body or 5 5 the animal of those particles, correct? side-by-side image of the MCM versus LCM. The tissue reaction to these BY MR. THORNBURGH: 7 7 Q. You were designated as somebody that particles would be no different to the tissue 8 would talk about evidence and studies regarding reaction to any filament in any part of the mesh. 9 9 degradation, right? But there will be a tissue reaction, 10 MR. THOMAS: We provided the studies 10 right? 11 11 on which he's prepared to testify. This is not one A. Yes. And when you increase the surface of the documents. 12 12 Q. MR. THORNBURGH: You only provided 13 13 area of a foreign body, that will increase the 14 14 studies that would support your position, not body's inflammatory response, won't it, sir? 15 studies that would show that your position was 15 Any increase in tissue reaction will 16 not be perceptible against the background of tissue 16 incorrect. 17 reactions of the implanted tape. MR. THOMAS: Now, we invited you to 18 ask him to review other things you wanted to be 18 When you increase the surface area, 19 prepared on, and you didn't. So this is -- if you 19 you increase the inflammatory response. Right, 20 want him to be prepared on it, he'll study it and 20 Doctor? 21 come back with an appropriate answer. He's not 21 MR. THOMAS: Object to the form of 22 prepared on it today. the question. 23 BY MR. THORNBURGH: 2.3 THE WITNESS: That's a general --24 Do you see where it says degradation, that's a general principle. 25 Doctor? BY MR. THORNBURGH: Page 544 Page 546 I am not prepared to respond to those And the principle is true. The questions today. It is not part of the preclinical principle -- the answer to that principle would be 2 3 data package that I put together to address yes. When you increase the surface area, you 4 degradation questions. 4 increase the inflammatory response. 5 You see where it shows the particles 5 Not in this case. A. that were lost? Do you see that? Do you see all 6 Q. In all other cases except for cases б 7 7 those flakes? against Ethicon products? 8 I can see particles in the 8 MR. THOMAS: Object to the form of Α. 9 photograph. 9 the question. 10 THE WITNESS: In any case where the 10 You're not suggesting to the ladies and gentlemen of the jury that there won't be an 11 addition of particles -- in any case where the 11 individual inflammatory response to each one of addition of the inflammatory reaction to a particle 12 those particles in tissue? could be perceived against a tissue reaction of the 13 14 A. It would pale by comparison to the implanted tape itself would be insignificant and 15 tissue reaction from the implanted tape. 15 unappreciable. But there will be an increased 16 BY MR. THORNBURGH: 16 Q. inflammatory response or an inflammatory response to 17 17 General scientific principle is when 18 the individual particle, correct? 18 you increase the surface area, you increase the 19 19 There will be an inflammatory inflammatory response, right? 20 response to that individual particle, but it will 20 MR. THOMAS: Object to the form of not be appreciated against the inflammatory response 21 the question. of the entire case. 22 THE WITNESS: That's a general 22 23 O. The phagocytes will try to gobble up 23 scientific principle. 24 that foreign body, won't they? 24 MR. THORNBURGH: Off the record for a 25 One will not be able to differentiate 25 minute.

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Page 547 Page 549 THE VIDEOGRAPHER: Off the video 1 was created after a review of that entire list of record, 4:14. both literature searches of R&D central file. But, 3 clearly, I didn't type all this and organize this (Short break.) 4 THE VIDEOGRAPHER: Back on the video and so on and so forth. 5 5 Now, are you -- you didn't come record, 4:25. 6 BY MR. THORNBURGH: prepared to talk about the number of the opinions 7 7 that you expressed in your expert report, correct? O. Dr. Barbolt, the studies that you've 8 listed for all of the designated topics that you 8 MR. THOMAS: Object to the form of 9 believed were relevant to those topics you included 9 THE WITNESS: That was not the within the list that we marked on the first day as 10 10 11 11 2241, correct? intention. BY MR. THORNBURGH: 12 12 MR. THOMAS: We marked the list --13 13 MR. THORNBURGH: Oh, I'm sorry. I For instance, you didn't come 14 apologize. Maybe we ought to do that. The problem 14 prepared to talk about the biocompatibility or lack 15 is I have handwriting on mine. I didn't bring 15 thereof of a mismatched mesh, right? 16 MR. THOMAS: Object to the form of 16 another copy. 17 17 BY MR. THORNBURGH: the question. What is that? 18 18 Q. Doctor --MR. THORNBURGH: Language in his 19 MR. THORNBURGH: Let's go off the 19 expert report. 20 20 record for a sec. MR. THOMAS: Sorry. 21 21 (Whereupon, a discussion was held off THE WITNESS: Mismatched mesh? 22 BY MR. THORNBURGH: 22 the record.) 23 2.3 THE VIDEOGRAPHER: 4:26, off the Q. Yes. 24 video record. 24 A. A lot of the topics in my expert 25 report are along the same lines of the topics that (Short break.) Page 548 Page 550 THE VIDEOGRAPHER: Back on the video we've been discussing here. There is a great deal record. It's 4:42. 2 of overlap. 2 3 This begins Tape Number 5, Volume 2 3 Well, in your expert report, on of the videotaped deposition of Dr. Thomas A. Page 12 of 27, you say: Movement of a mesh from its 5 Barbolt. original site of implantation can result from б BY MR. THORNBURGH: б compliance mismatching. This is a mesh that is 7 7 Dr. Barbolt, we're going to mark as stiffer in terms of bending rigidity than Q. an exhibit a list of studies that you chose which 8 surrounding the tissue. you believe were relevant to the 30(b)(6) topics 9 Are you prepared to talk about that you were designated to discuss. It's been 10 Ethicon internal documents; for instance, documents 10 from Dr. Trzewik regarding the bio -- the marked as 2262. 11 11 (Document marked for identification 12 biocompatibility or mismatching of mesh? 12 13 13 as Exhibit T-2262.) Yeah. I'd have to look at that --14 BY MR. THORNBURGH: 14 I'd have to look at my expert report and then look 15 Doctor, the 2262 list of studies are 15 at the reference to that particular article. the studies that you chose that you believe were 16 Did you look at any of Dr. Trzewik's 16 relevant to the topics you were designated to 17 internal documents before you came here today? 17 18 discuss, correct? 18 MR. THOMAS: To prepare for this 19 19 A. Yes, that's correct. deposition today? 20 Q. Did anybody help you compile this 20 MR. THORNBURGH: Yes. 21 21 list? BY MR. THORNBURGH: 22 22 I mean, if you want to go there, I'll A. Yes. 23 Q. Who helped you compile the list? go there. I'm ready to go there. If you want to Counsel's staff or Ethicon personnel. 24 talk about the tissue and the biomechanical 24 properties of tissue compared to the biomechanical 25 Ethicon personnel created the first list. This list

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Page 551 Page 553 properties of mesh, which can cause increased trial, which is coming up. inflammatory response as a result of mismatching, I 2 MR. THOMAS: You owe me a jordi date, am ready to do it. But I need to know from you if 3 too. 4 you're ready to do it. MR. THORNBURGH: Well, I'm trying --5 Well, I came prepared to talk about 5 you just let me know yesterday, I think it was, that Α. 6 the preclinical studies that we've got in front of the date I proposed was not a good date, so I am 7 7 trying to get another date for you. I hope to have us and behind us. 8 MR. THOMAS: Short answer is no. 8 that by today or tomorrow. Okay? 9 9 MR. THORNBURGH: Okay. MR. THOMAS: Okay. BY MR. THORNBURGH: 10 MR. THORNBURGH: I am going to give 10 11 11 And that's one example of expert you a date before the trial. 12 opinions that you have that you're not prepared to 12 MR. THOMAS: Okay. Are you finished 13 13 discuss today, correct? now? 14 14 A. That's correct. MR. THORNBURGH: No. I'm just trying 15 MR. THORNBURGH: Are you going to 15 to get some stuff on the record. 16 MR. THOMAS: What was the number of 16 give me a date where we can take Dr. Barbolt's that last exhibit? expert deposition? 17 17 18 18 MR. THOMAS: To the extent that we MR. THORNBURGH: 2262. 19 intend to offer Dr. Barbolt in areas beyond the 19 MR THOMAS: Thank you. 20 20 BY MR. THORNBURGH: scope of the 30(b)(6) designation, yes. 21 MR. THORNBURGH: Well, I mean, I have 21 Do you believe Ethicon should have 22 22 all kinds of external Ethicon -- external scientific done anything different in terms of the language 23 23 they used in the IFU that we looked at regarding articles on porosity. 24 Now, porosity was an issue regarding degradation and the inflammatory response? 25 preclinical studies, but he's offering opinions 25 MR. THOMAS: Object to the form; Page 552 Page 554 regarding pore size in his expert report. I want to 1 scope. have an opportunity to cross-examine him on non --2 2 THE WITNESS: I am here to represent 3 both internal and external documents that we have. 3 Ethicon with respect to these preclinical studies 4 Now, if he's prepared to do that now, 4 and their results. because we talked about porosity, then I'll do that. BY MR. THORNBURGH: 5 But if you're going to offer him up for an expert 6 б Based on the preclinical studies, 7 deposition on those issues, then I will reserve that 7 including the five-year and seven-year data from the 8 for another time. 8 ten-year dog study and the other studies that showed 9 MR. THOMAS: I think that the option 9 chronic inflammation, do you believe that Ethicon is to reserve for another time, and we'll decide 10 should have done anything different, added any 10 whether another time is necessary. And if we don't 11 additional language, such that -- any additional 11 12 agree, I think the magistrate has already spoken to 12 language such that information would have been 13 that. But I feel confident we'll agree. 13 disclosed to physicians in the IFU? 14 MR. THORNBURGH: So I don't need to 14 MR. THOMAS: Object to the form of 15 go through like degradation studies and --15 the question. MR. THOMAS: No. He's asking you from a preclinical 16 16 MR. THORNBURGH: -- studies that he 17 17 perspective whether you would change the IFU. wasn't prepared to talk about? 18 THE WITNESS: Yes. As I indicated, 18 19 19 MR. THOMAS: Correct. the IFU is not the responsibility of preclinical. 20 MR. THORNBURGH: We can raise that at 20 It is responsibility of medical 21 affairs folks, the regulatory folks, taking input 21 another time and, hopefully, we can agree on a time before --22 from all areas of product development, including 22 23 MR. THOMAS: A time and scope. I 23 preclinical. 24 MR. THOMAS: He's asking you from a 24 agree. 25 perspective of preclinical whether you would, from 25 MR. THORNBURGH: A time before the

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Page 555 Page 557 1 your preclinical experience, when you review the No, I don't think that's necessary. A. preclinical studies under the designations that have I think all surgeons know that a permanent implant been made, whether you as Ethicon would change the is going to be associated with some low level of IFU from a preclinical perspective. chronic inflammatory reaction for the life of the 5 THE WITNESS: No. 5 patient. 6 6 BY MR. THORNBURGH: MR. THORNBURGH: Move to strike after 7 7 Adding information in the IFU the word, no. 8 regarding the surface degradation is not a change 8 Pass the witness and reserve some 9 9 that you think Ethicon should have made? time for cross-examination. 10 MR. THOMAS: Object to the form of 10 MR. THOMAS: Let's take a break, 11 11 the question. please. 12 THE WITNESS: It's not useful 12 THE VIDEOGRAPHER: It's 4:53. Off 13 13 information for the surgeon when there is no impact the video record. 14 14 on molecular weight and tensile strength of the (Short break.) 15 fiber. 15 THE VIDEOGRAPHER: Back on the video 16 BY MR. THORNBURGH: 16 record, 5:17. 17 17 Adding information to the IFU from 18 18 a -- regarding the chronic inflammatory response **EXAMINATION** 19 that you observed in all of your preclinical 19 20 studies, you don't believe that more definitive 20 BY MR. THOMAS: 21 21 language regarding the chronic inflammatory response Q. Dr. Barbolt, would you pick up 22 should have been added to the IFU? Exhibit 2262, please. 22 2.3 23 MR. THOMAS: Object to the form of Okay. A. 24 the question. 24 Q. And Exhibit 2262 is titled, 25 THE WITNESS: The tissue reaction to "Deposition Subject Matter." And this is a document Page 556 Page 558 polypropylene-based material is well understood. that you described towards the end of your It's discussed in detail, including the chronic deposition where you identified for counsel for 2 3 inflammatory reaction to Prolene sutures in the plaintiffs all of those topics for which you 4 19 -- 1960s NDA submission. gathered information to be responsive to the 5 The whole history of studies from the questions today. Correct? 6 Yes, that's correct. б mid '60s to current day has demonstrated a very A. 7 consistent tissue reaction profile to implanted 7 And this multi-page document Q. obviously lists many studies. Do you have those 8 polypropylene-based devices. 8 9 BY MR. THORNBURGH: 9 studies with you here today? So there is a chronic inflammatory 10 Yes. They're in the various binders 10 that you see around that are entitled with the response, not a temporary one, correct? 11 11 specific subject matter topics as are listed in 12 MR. THOMAS: Object to the form of 12 13 the question. 13 these sheets. 14 THE WITNESS: It's well understood 14 Q. How many boxes of binders did you 15 that the initial reaction is transient and can verge 15 bring to the deposition today? to a chronic inflammatory reaction and a fibrotic 16 Oh, I think there was 18 or 20. 16 A. 17 18 or 20 binders? Q. 17 response with more or less inflammatory cell 18 infiltrate, well documented in all the implantation 18 Α. Binders. 19 The first one on the list is for the 19 studies. 20 BY MR. THORNBURGH: 20 specifics of all testing related to the TVT 21 You don't believe that Ethicon should 21 products. 22 have added additional language in the IFU that 22 Now, you understand there are discussed the chronic inflammatory response 23 multiple TVT products? specifically using the word, chronic inflammatory 24 A. Yes. 25 25 response, in the IFU? And so you went back and searched for

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Page 559 Page 561 all the testing that you could find for all of the the scope. 2 TVT products? THE WITNESS: Yes. 3 3 Yes. Each of the individual TVT BY MR. THOMAS: A. 4 products are -- and the data supporting their And the first five studies in your preclinical studies are assembled in individual 5 degradation section are studies submitted to the FDA binders and titled according to the TVT product. in connection with the Prolene suture NDA, correct? 7 7 During the design and development That's correct. 8 stages, including but not limited to, at least for 8 Q. And let's talk about those briefly. 9 9 this section, it's porosity testing, particle loss, Study of tissue reaction to the colorless and 10 degradation, and leaching, correct? pigmented monofilament polypropylene suture in the 11 11 A. Yes. rat, rabbit, and the dog. Just tell me briefly what those 12 Q. 12 And the first one that we have listed 13 13 here is degradation. And you have notebooks here studies are. 14 14 for degradation? A. These were tissue reaction studies in 15 A. Yes. 15 three species of animals, with colored and 16 Correct? 16 O. non-colored suture, looking at tissue reaction over 17 And those notebooks contain 46 17 time. 18 18 different documents? Q. And how long were those studies? 19 Α. That's correct. There are 40 19 A. The rat study was two years. That's 20 different -- 46 different studies or documents 20 the lifetime of a rat. 21 related to potential degradation of TVT products. 21 The dog study was two years. And the 22 22 Now, the TVT, as you've explained in rabbit study was 90 days. your examination, didn't come into existence until 2.3 And are those considered long-term 23 Q. the late '90s, right? 24 studies? 25 That's right. The work started in 25 A. A. The two-year rat as a lifetime study Page 560 Page 562 the '97 time frame or so, and then I think the is certainly a long-term study, as with the dog 510(k) approval was in early 1998. 2 study of a two-year duration. 2 3 And the information that you list in 3 And what's the purpose of doing a 4 response to the degradation designation begins in 4 tissue reaction study to a polypropylene suture in 5 1964; is that right? an NDA? б б Yes, that's correct. A. A. So for the purposes of a suture, the 7 7 And it runs in chronological order most important thing that needs to be determined is Q. 8 all the way up until 2007, right? 8 the tissue reaction of the material over time. 9 Yes, that's correct. 9 And you have reviewed the tissue A. reaction studies from the NDA? Why did you include studies that 10 10 Q. predated the TVT? 11 Α. Yes. 11 Well, the material used to 12 12 And are the tissue reaction findings 13 13 manufacture TVT mesh is Prolene polypropylene for the polypropylene suture approved by the FDA similar to the findings that you have reviewed with 14 filaments. And a great deal of work was done in the 14 mid '60s and beyond, demonstrating biocompatibility 15 respect to Prolene mesh? 15 of that product and essentially received FDA 16 MR. THORNBURGH: Objection to the use 16 17 of the word, approved, as well as outside the scope 17 approval. 18 Q. What is an NDA? 18 of his designation. 19 THE WITNESS: The tissue reaction is 19 An NDA is a new drug application. 20 And at the time of the development of Prolene 20 very similar. suture, polypropylene sutures were considered drugs. 21 BY MR. THOMAS: 21 22 And did Ethicon go through a new drug 22 Okay. And you understand that in 23 23 application in order to have FDA approve the order for Ethicon to be able to market this polypropylene suture that's now used in TVT mesh? 24 polypropylene suture, known as Prolene suture, the 24 FDA had to approve the NDA? 25 MR. THORNBURGH: Objection; beyond

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Page 563 Page 565 1 THE WITNESS: No. The tissue 1 MR. THORNBURGH: Objection; move to 2 strike. reaction is pretty consistent over time. And in 3 THE WITNESS: Yes. That's an many studies, there's a diminution of the tissue 4 approval process. It's not like a 510(k) clearance. 4 reaction over time. The kinds of qualitative 5 BY MR. THOMAS: 5 characteristics seen with Prolene polypropylene 6 And as a matter of fact, in order to suture are the very same kind of qualitative changes Q. 7 7 market this suture, this Prolene suture, Ethicon had seen around filaments of the Prolene polypropylene 8 to get approval from the FDA for the language that 8 mesh. 9 9 went in the IFU for the Prolene suture? BY MR. THOMAS: 10 MR. THORNBURGH: Objection. 10 And in any of the studies that you've 11 11 BY MR. THOMAS: identified in the 46 studies in the degradation 12 12 section on T-2262, did you identify any failure Q. Did you know that? 13 13 MR. THORNBURGH: Objection; lack of issues with the mesh or the sutures due to any 14 degradation of the mesh? 14 foundation, outside the scope. 15 THE WITNESS: That's correct. 15 A. No. And I would point to Tab 5, 16 16 BY MR. THOMAS: where for the purposes of the Prolene suture NDA, 17 there was a two-year study where Prolene suture was And the language -- strike that. 18 So after the NDA studies, you pick up 18 implanted and tensile testing was conducted, and 19 a number of studies that begin in the '70s and go 19 there were no consistent changes in the strength of 20 through the '80s, into the '90s, all the way up to 20 suture over time. 21 the time when you start involving testing for the 21 So in these 46 studies that you were Q. 22 TVT device, correct? 22 able to retrieve and review, did you find any issues 23 A. 23 with degradation of the polypropylene suture that Yes. 24 Q. And why did you include those studies makes up both Prolene suture and Prolene mesh to 25 in your degradation section? cause you any concern in the preclinical area about Page 564 Page 566 Those studies are part of the any adverse effects from the use of that suture due 2 database that -- that shows that the tissue reaction 2 to degradation? 3 to Prolene polypropylene filaments is very 3 MR. THORNBURGH: Objection. 4 consistent over time. 4 THE WITNESS: No. 5 5 Now, in -- in the studies that have BY MR. THOMAS: been conducted since 1964, when you conduct a tissue б The next section in 2262 is called б 7 7 reaction study such as those listed in T-2262, is leaching. And, again, this is the specifics of all 8 degradation something that's always a component of a 8 testing related to TVT products during the design 9 study? 9 and development stages, including but not limited to 10 A. Yes, for absorbable or non-absorbable 10 leaching. And what is leaching, for the jury? sutures. In this case Prolene suture is a 11 11 non-absorbable suture. One needs to monitor what 12 Leaching is the movement of a the appearance of the suture looks like over time so 13 substance or substances from the body of an implant 13 14 that one can conclude there's no visible evidence of 14 to the surrounding tissues. Now, the leaching section of your 15 degradation from these tissue reaction studies. 15 That's always a component of a tissue reaction 16 disclosure identifies 91 different documents in 16 17 response to the leaching. 17 study. 18 Q. I am going to get into the seven-year 18 Why are there so many documents that 19 dog study here in more detail in a little bit. But 19 you identified in response to the leaching issue? 20 from any of the 46 studies that you identified in 20 Every implantation study is an 21 21 the degradation studies that you have brought here opportunity to evaluate any potential consequence of leaching from an implanted device. And there are, 22 with you today, did you find any degradation of any 22 Prolene suture or Prolene mesh that you saw created 23 as I recall, some studies in here that look at 24 an increased inflammatory response? 24 extracts of the device and administration of those 25 25 MR. THORNBURGH: Objection. extracts to animals to look at whether or not there

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Page 567 Page 569 is adverse reactions, for example, an intracutaneous animals. And any leachables that would have adverse reactivity test. impact to the surrounding tissues would be revealed 3 in a histomorphological evaluation of the section. And these studies are conducted for 4 products in variation -- in products over time and 4 Now, counsel made a number of 5 for many of the iterations of TVT mesh. 5 questions about the fact that leaching is not a 6 Now, you have different categories of primary or called out endpoint in each of these 7 7 documents in the leaching section of this exhibit. studies. 8 You have one section called in vitro. What is that? 8 Is leaching something that a 9 These are studies where the device is 9 pathologist looks for in any in vivo study? 10 extracted to maximize leachables, and in this case 10 Absolutely. A pathologist would be 11 11 you would say leachables/extractables, because looking at the tissue reaction at the interface of 12 sometimes the extraction mediums can accelerate the 12 the implant and the surrounding tissues. And if there were increased reaction, there would be a 13 movement of substances from a mesh to the 14 surrounding tissues. 14 result of either the implanted material or any 15 These extracts are then tested in in 15 leachables or a combination of both. 16 vitro systems which are very sensitive. Now, the leachables we've talked 16 17 And what is an in vitro system? 17 about include the additive package that you were Q. 18 A. In vitro system is a cell culture 18 asked a number of questions about, correct? 19 system. And with respect to these studies, they 19 A. Yes. 20 20 Q. The Santonox R, the DLTLP, and the would be known as in vitro cytotoxicity assays. 21 They're in a laboratory dish? 21 others in the John Karl memorandum, do you remember Q. 22 those? 22 A. That's correct. 2.3 2.3 Q. Okay. A. Yes, that's correct. 24 A. They are cells in culture and petri 24 O. And those additives have been in the dishes, or nowadays in wells of 96 well plates where product since the beginning, as that memorandum Page 568 Page 570 cells are incubated, and then the extracts are added described. Do you remember that? 2 to the cells. 2 A. That's correct. 3 And then an evaluation is made, as we 3 And the in vivo section which begins 4 discussed earlier, whether or not there's any impact on Number 35. Number 35 is an NDA study that's 5 on cell viability in accordance with standard USP March 10, 1964, correct? б scoring scheme, as we discussed earlier. A. Yes. б 7 7 If we look at your chart for So from March 10, 1964 all the way up O. Q. 8 leaching, beginning with Number 7 all the way 8 to March 11, 2010, you have in vivo studies where through Number 34, you have in vitro studies that you've looked at the effect of any leachables on you've reviewed for the cytotoxicity of Prolene, 10 these in vivo studies? 10 11 correct? 11 Α. That's correct.

A. Yes, that's correct.

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- Q. And you reviewed and prepared to testify about each of those studies, to talk about how they relate to the leaching issues, if any, associated with Prolene suture in mesh?
- 17 A. Yeah, that's correct. And we have 18 talked about some of those today in the context of 19 TVT mesh and the 510(k) submission of TVT original.
- Q. Now, beginning with Number 35 all the way to Number 91, you have in vivo studies for leaching. What are the in vivo studies for leaching?
- A. These -- these would be implantation studies where the materials are implanted in

MR. THORNBURGH: Objection. THE WITNESS: FDA approved the original product, Prolene suture. And that suture contained those additives.

And the additives in the suture

package that we talked about before at some length,

all those additives were approved by FDA, weren't

20 BY MR. THOMAS:

Q. And in any of the in vivo studies

beginning on Page 35 -- on Number 35, all the way up to 91, did you find any adverse effects due to

23 to 91, did you find any adverse effects due to

leaching from the Prolene suture or the Prolene meshin those results?

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they?

Page 571 Page 573 1 1 A. No. A. The tissue reaction to the TVT mesh 2 Q. Now, why are the results from in was very comparable to the non-in vitro cytotoxic vitro tests different from the results in in vivo 3 Prolene flat mesh, in that there were -- was no 4 tests sometimes? impact on wound healing over time on the face of the 5 5 In vitro tests are very quick to implant. Α. conduct. They are relatively inexpensive. However, 6 Q. And what does that mean in terms of 7 7 they only provide directional information and not whether there is a cytotoxic effect of Prolene mesh 8 definitive information. 8 in vivo? 9 9 What do you mean by that? Now, the least impact might be 10 Well, they are studies conducted 10 delayed wound healing, and that was not observed. A. outside the body. Artificial environment. 11 If there were a more severe impact as 11 12 And if you have a positive 12 a result of leachables, that would have translated 13 into an increased tissue reaction. 13 cytotoxicity test in vitro, what does that mean to 14 14 the question of whether the substance is going to be In other words, rather than minimal 15 cytotoxic in vivo or in an animal? 15 to mild reactions, we might have seen moderate to 16 16 Again, that would be a watch owl, marked reactions. 17 that is a directional information. And then you 17 O. Was there any evidence in this 28-day 18 18 would need to do more relevant in vivo studies to rat study that you conducted to determine the extent 19 determine if the in vitro cytotoxicity translated it 19 to which the TVT mesh in the Ulmsten device was 20 into any in vivo cytotoxicity or any adverse impact 20 cytotoxic, that it was, in fact, cytotoxic in vivo? 21 on wound healing. 21 Any evidence at all? 22 22 O. And in this case, as discussed in A. No. there was not. 2.3 23 your direct examination, there was a positive Now, in the category that we have for cytotoxicity test in vitro for the TVT device, that section, it's Category 4, and you don't need to 25 correct? go to it unless you want to. Page 572 Page 574 1 1 A. That's correct. A. 2 MR. THORNBURGH: Objection. More 2 Q. There are three other -- why don't 3 than one. 3 you go ahead. It's about four from the back. 4 BY MR. THOMAS: 4 Four from the back. Okay. Yes. 5 5 So what did Ethicon do when it had There's five tabs. 6 б its positive cytotoxicity response to follow up on And the first one is a study that we Q. 7 7 just discussed, the 28-day rat study? that? 8 8 Ethicon conducted a 28-day study in Yes, that's correct. Α. rats, looking at the implantation -- the tissue 9 Q. And that was a GLP study, correct? 10 reaction to the -- or after the implantation of TVT 10 A. Yes. 11 11 mesh. What does it mean to be a GLP study? Q. 12 12 You were designated as the person A GLP study would be a study 13 most knowledgeable regarding a 28-day intramuscular 13 conducted in compliance with the FDA good laboratory tissue reaction study in rats of polypropylene mesh 14 14 practices regulations. in the TVT (Ulmsten) device (PSE 97-0197); is that 15 As we discussed earlier, all studies 15 correct? 16 are conducted in accordance with SOPs and standard 16 A. 17 17 policies and procedures. 18 O. And that's the study to which you 18 An FDA GLP study has an additional

Q. The next three entries in Category 4, where you're the person most knowledgeable about this 28-day intramuscular study that we've just been

level of scrutiny, and that is outside, independent

the final report in comparison to the raw data to

ensure that they reflect individual animal data.

review of various phases of a study and a review of

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19

22

23

just referred where Ethicon actually did an

That's correct.

implantation study in rats to determine the extent

And what was the finding of that

to which the TVT mesh was cytotoxic in vivo,

19

20

22

23

24

correct?

25 study?

A.

Q.

Page 575 Page 577 discussing, deals with a mesh called Vypro mesh, and 91-Day Tissue Reaction Study"; is that right? 2 a cytotoxicity assessment for Vypro mesh. Yes. It's tab -- its Tab 5 here on 3 3 What is Vypro mesh? this list. 4 4 Vypro mesh is a composite mesh Q. And that tests the Prolene 5 mil 5 consisting of the filaments of polypropylene and 5 mesh, correct? 6 6 polyglactin 910 yarn. Α. That's correct. 7 7 Q. And is Vypro mesh a hernia mesh? Q. And the Vypro mesh, a couple of 8 A. Yes. It would be considered --8 versions of the Vypro mesh? 9 9 Q. And did a preclinical test on Vypro mesh determine whether it was cytotoxic? 10 Q. 10 And there were no cytotoxic findings 11 11 Yes. As part of the development of as a result of that 91-day study for either Prolene 12 Vypro mesh, some biocompatibility studies were 12 5 mil mesh or the Vypro mesh, correct? 13 13 conducted, and the in vitro cytotoxicity study was That's correct. There was no 14 one of them. 14 evidence of increased tissue reaction in the Vypro 15 And what was the finding of the Vypro study in spite of there being evidence of in vitro Q. 16 cytotoxicity in a manner very similar to a TVT mesh. 16 cytotoxicity test? 17 17 The last document on the leaching Vypro mesh was cytotoxic in vitro. 18 18 Q. And so what did the company do? Did schedule, going back to where you were, Number 6, is 19 it not market it? 19 a May 8, 2013 document, and it's titled 20 20 "Biocompatibility Risk Assessment For The Gynecare Well, as part of the biocompatibility 21 assessment, they then conducted a intracutaneous 21 TVT Product Family." 22 reactive study looking at extracts of the suture What is that? that would get leachables and extractables and then 2.3 23 Let me catch up to you, David. ejected them into the skin of rabbits to look at 24 What's the tab number? evidence of local irritancy. 25 Q. Tab 6. Page 576 Page 578 1 And what was the finding from that Tab 6. This was a technical file that was updated just recently at the request of the 2 intracutaneous study? 3 It was negative. There was no European Union for the whole family of TVT products, 4 evidence of irritancy. The reaction was negligible. 4 essentially a compilation of the history of TVT 5 So once it passed the intracutaneous family of products, outlining component materials, 6 б in vivo test, did the company then get clearance to tests -- biocompatibility testing that was 7 7 market the product? appropriate in accordance with tissue contact 8 8 Yes. categories, and an evaluation of the Α. 9 Q. So at least in one other circumstance 9 biocompatibility results coming to a final 10 in which you have been involved and the company has assessment of whether or not the biocompatibility of been involved, there has been a positive 11 Gynecare family of products conducted, in light of 11 12 cytotoxicity test for a mesh that you followed up. the current version of ISO 10993 standards, not And then after doing in vivo testing, you determined 13 realizing that these standards changed every five 13 14 that it's appropriate to market the mesh? years and that the standards in place in 1997 would 15 Yes. And I should say in addition to 15 be different than the ones in place in 2013. the intracutaneous reactivity test where extracts 16 So some of the goal of this exercise 16 17 was to apply current 2013 standards against the 17 are injected into rabbit skin, of course there was 18 an implantation study that we discussed at length, I 18 biocompatibility testing program conducted for TVT 19 think these last few days, and that is the 91-day family of products to see if, in fact, the 19 20 study where the tissue reaction to Vypro mesh was 20 biocompatibility risk assessments done at the time 21 compared to many other meshes, and the tissue still hold. reaction was found to be acceptable with appropriate 22 22 Q. And that would relate also back to 23 23 tissue integration. the testing done on polypropylene sutures back in 24 1964 with the NDA, wouldn't it?

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MR. THORNBURGH: Objection.

25

24

The tissue reaction study you're

25 talking about now is T-2242, titled "Exploratory

Page 579 Page 581 THE WITNESS: Yes, that's correct. 1 1 testing? In the same manner that we've discussed and 2 A. 3 leveraged that early data on poly -- Prolene And why did you pick the documents Q. 4 polypropylene fiber for suture, it's also relevant that you have here, beginning in 1964, the 38 documents, going all the way up to 2007? Why did 5 for Prolene meshes and TVT. 5 you include those? 6 BY MR. THOMAS: 7 7 Q. And does the biocompatibility risk A. Particles were observed in the 8 assessment for the Gynecare TVT product family of 8 Prolene suture NDA submission. And as I pointed out 9 9 May of 2013 include a leaching component? this morning, they resulted in an inflammatory 10 A. Yes. reaction very similar to that reaction around the 11 11 O. And so this product -- the studies filaments of the suture. You talk about fragments and you've 12 and the documents that you have in the leaching 12 O. 13 talked about particles. Are fragments and particles 13 section of your documents that you brought with you 14 today covers some 49 years, correct? 14 different? 15 MR. THORNBURGH: Objection. 15 As I mentioned this morning, I see a A. 16 16 THE WITNESS: Yes. big difference there. 17 BY MR. THOMAS: 17 A fragment of a suture is likely to 18 18 And in those 49 years of 91 have been related to the swaging process or the 19 documents, did you find anything that suggests that 19 cutting lengths of suture, or a fragment of suture 20 there's anything leaching from polypropylene 20 gets attached to the suture and then gets implanted 21 with it. 21 sutures -- excuse me. Strike that. 22 22 That's different than the In your 49 years of documents, you 23 covered some 91 different documents. Did you find 23 microparticulates that we discussed earlier, looking any evidence of any leaching in vivo that led to any at data from the seven-year dog study. adverse reaction in a preclinical study? 25 And so the 38 studies that you've Page 580 Page 582 1 MR. THORNBURGH: Objection. included in your section of particle loss from the 2 THE WITNESS: No. period, 1964 to 2007, you've looked for the extent 3 BY MR. THOMAS: to which there's been any adverse consequences noted 4 The next section that I have in this in preclinical studies from any kind of particle 5 disclosure, which is T-2262, is the specifics of all loss of sutures and mesh? testing related to TVT products during the design б Yes, although fragments are noted in б 7 and development stages, including particle loss. 7 the NDA submission and in the Postlethwait study that we discussed earlier. In the early going, in the 8 Now, tell me the difference between 8 the clinical and the preclinical analysis of 9 development of Prolene suture, I've not seen particle loss. 10 personally in any of the implantation studies that 10 11 MR. THORNBURGH: Objection. 11 I've conducted any sort of fragment of filament next THE WITNESS: The preclinical 12 to a filament in an implantation study. 12 13 assessment of particle loss is one that can be done 13 And you talked before about the particle in the NDA study and the kind of reaction 14 in any implantation study where the implant is 14 15 visualized against the surrounding tissue. And if 15 that -- tissue reaction with respect to that there are any particulates there, they would be 16 particle. 16 17 observable. 17 With the particle in the NDA study, 18 I am not sure about the clinical 18 did you find any adverse inflammation or tissue arena. I don't know that I can speak to that. 19 reaction that had any consequences to you for a 19 20 BY MR. THOMAS: 20 preclinical perspective? 21 Okay. The clinical arena involves 21 A. No. 22 humans, and that's not work that you do? 22 Q. Why? 23 A. That's correct. 23 It was the same kind of reaction And you are aware of the particle 24 around the fragment as there was around the suture. 24 25 25 loss issues insofar as they relate to preclinical Think about a tissue reaction around

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Page 583 Page 585 the earth and a tissue reaction around the earth and the Pariente study. 2 moon. The tissue reaction around the earth is A. I've got the 2260. I'm looking for 3 around the interface of the earth and the 2130. atmosphere. And then there is the moon on the side 4 Q. I'll get this copy to you. 5 5 of the earth with a very similar reaction around its Maybe it was discussed yesterday, and A. interface with substance and atmosphere. it's in this stack, yeah. I can probably get it, 7 7 You answered the question at least David. 8 seven or eight times today about whether more 8 It's all right. I've got another Q. 9 9 material implanted leads to an increased tissue copy. reaction, and you said as a general proposition, 10 10 The Pariente study is the particle 11 11 that's true. Is that fair? loss study that counsel discussed with you at length 12 12 at T-2260. Α. Yes, I think so. I think that's a 13 13 general principle. Again, as I also mentioned, the If you go to the first page of 14 details and particulars need to be determined on the 14 T-2260, down in the lower right-hand corner, it 15 basis of an implantation study. 15 reads: Mechanical testing was performed with a 16 And -- and how much additional 16 7-centimeter length sample (n=5) on an Instron 4466 17 material -- strike that. 17 with a 500-Newtons sensor using the software Series 18 18 Are you able to evaluate the extent IX-7 to program the setup. 19 to which additional material creates a tissue 19 What is an Instron machine? 20 response that's unacceptable from a preclinical 20 An Instron machine is a piece of 21 21 equipment that can determine the tensile strength of study? 22 22 A. Yes. I think in every implantation a fiber by pulling at both ends and determining the 23 study, one can make that determination. 23 strength at -- the force at which it breaks. 24 In your evaluation of all of the 24 And how did Pariente use an Instron 25 studies in the particle loss section of your machine to test the extent to which particles were Page 584 Page 586 designation, the 38 studies over 43 years, did you shed from the meshes that they tested? find any unacceptable tissue response to any 2 Well, it looks like he put each mesh 2 3 particles in those studies? 3 on the Instron machine and pulled it until it broke. 4 A. Yeah. The only --4 And as I look on Table 1 of that 5 MR. THORNBURGH: Objection. study, it looks like each of the meshes were pulled, б THE WITNESS: The only studies that б as one might expect, a different peak load, 7 7 even talk about particles or fragments is the NDA depending on their biomechanical characteristics. work in a study done in 2002, Tab 33, that was done 8 And at what point in this process 9 specifically to look at whether or not particles 9 were particle loss measured? Are you able to tell would be present after implantation of lengths of 10 that? 10 11 TVT tape. And, in fact, none were observed. 11 A. Could you repeat the question? 12 12 BY MR. THOMAS: Yes. At what point in this 13 Would you get 2260 in front of you, 13 experiment were the particle losses measured? 14 please. That's the Pariente study. I don't have 14 A. I think at break. the number of the rabbit study. 15 Q. Okay. 15 MR. THOMAS: Do you happen to have I think at break. As I look at this 16 16 A. 17 Figure 3, there's a break, obviously, and then 17 that, Dan? 18 MR. THORNBURGH: The test number or 18 there's a drop in force because there is a break. 19 Is 2260 a preclinical study that the exhibit number? 19 20 MR. THOMAS: The exhibit number. 20 Ethicon conducts to evaluate particle loss? 21 21 Ethicon did not conduct this study. I do have it. I'm sorry. A. 22 MR. THORNBURGH: 2133. 22 Does Ethicon -- strike that. Q. 23 BY MR. THOMAS: 23 Is this a preclinical study? 2133. Can you get 2133 and 2260? 24 This is kind of bench-top 24 Α. 25 biomechanical testing. 2133 is the March 5, 2003 rabbit test, and 2260 is

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	Page 587		Page 589
1	Q. What is the difference between	1	T-2130?
2	bench-top biomechanical testing and preclinical	2	A. That's 33. 2133?
3	testing?	3	Q. Yes.
4	A. Well, I guess it can be considered	4	A. You keep saying 30.
5	preclinical because it's done before, you know, the	5	Q. I'm sorry. Thank you.
6	product gets to clinic. But it's different than	6	A. What was the page number?
7	preclinical in my mind that has to do with in vitro	7	Q. Page 35.
8	or in vivo experimental studies with products in	8	A. Okay.
9	animals.	9	Q. You see under the category,
10	Q. Okay. And why is it important to you	10	approximate average thickness of fibrous tissue
11	to measure products in vitro or in vivo in animals?	11	located between the mesh fiber bundles strike
12	A. Well, because any bench-top is an	12	that. Let me start over again.
13	artificial environment designed to look at a	13	On Page 35 of Exhibit T-2133, there
14	specific parameter under certain conditions. And in	14	is a table called "Histological Observations,"
15	my mind, an in vivo study where there is an	15	correct?
16	implantation of a product, it's more clinically	16	A. Yes.
17	relevant because it simulates the patient	17	Q. And what are histological
18	environment.	18	observations?
19	Q. If you look at T-2130, this is the	19	A. These are observations by the study
20	two-week rabbit study; is that correct?	20	pathologist looking at evidence of tissue reaction
21	A. 2133?	21	and integration and the evidence of fibrosis or any
22	Q. Yes.	22	other impact of the surrounding tissues.
23	A. Yes, a two-week rabbit study.	23	Q. And there is a category that's there.
24	Q. And if you look at the abstract on	24	It says: Inflammatory cell infiltrates only
25	Page 3, the objectives of the study were to compare	25	associated with the mesh.
	Page 588		Page 590
1	the mechanical strength and histological response of	1	What is that? Right in the middle.
2	Prolene mesh and Prolene Soft mesh in skeletal	2	A. Yeah. It looks like they're calling
3	muscle of the rabbit, correct?	3	out the tissue reaction associated with the mesh
4	A. Yes.	4	versus a tissue reaction to the skeletal muscle
5	Q. And this is the same Prolene mesh	5	which was injured during the implantation process.
6	that's used in TVT?	6	Q. And in the far right-hand corner
7	A. Yes, that's correct.	7	excuse me the far right-hand column, there is a
8	Q. And one of the specific endpoints of	8	specific category for mesh particles within muscle.
9	this study, this two-week rabbit study, T-2130, is	9	And for each one of these animals,
10	to evaluate the extent to which the mesh shed	10	they specifically look in the histology to try to
11	particles inside the rabbit, correct?	11	identify any particles that may have been in the
12	A. Yes, that's correct.	12	rabbit in two weeks; is that correct?
13	Q. And how did the study do that?	13	A. That's correct.
14	A. The implant site was explanted and	14	Q. And do they find any particles in the
15	the tissue reaction was assessed. And, obviously,	15	histology for any of the rabbits?
16	that would include the implant and any particulates	16	A. No. No particles were observed for
17	that might be present, as that was one of the called	17	any for any at any implantation site.
18	out objectives in this particular experiment,	18	Q. And this is a two-week study. Does
19	although for me, any implantation study I would be	19	the fact that this is a two-week study as opposed to
20	looking for particulates, but this was called out in	20	a six-month study or a ten-year study have any
21	this study.	21	impact on whether this is a valid study to determine
22	And so they would look at the tissue	22	the extent to which mesh particles may be found
23	reaction to the mesh itself and any evidence of	23	after implantation of mesh?
24	particulates in the surrounding tissue.	24	A. I think at a two-week post
25	Q. If you go to Page 35 of that study,	25	implantation period is sufficient time for a tissue

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Page 591 Page 593 reaction and a fibrotic response to occur around any observations of encapsulation that were observed that were not confirmed upon histological review. particulate if it were present. 3 3 Okay. And the histology in this Is that fair? two-week rabbit study, 2133, was consistent with all 4 A. That's correct. I recall that 5 of the other Prolene tissue response tests that 5 discussion. you've gotten since 1964, correct? 6 Q. And you were the person who conducted 7 7 Yeah, that's correct. If you look at the histological review, correct? 8 the inflammatory cell --8 Α. Yes. 9 9 MR. THORNBURGH: Objection. Sorry. And how is it that what might appear 10 If you can just give me a hair of a 10 on a microscopic level to be encapsulation, upon 11 11 second --histologic review, may prove something else 12 12 altogether? THE WITNESS: I'm sorry. 13 13 MR. THORNBURGH: -- I'd appreciate A. Yeah. The deficiency of a 14 14 it. I've got to get an objection in. macroscopic observation is that it cannot see 15 THE WITNESS: That's fine. 15 through the tissue. For example, if I were to put 16 this piece of paper on top of this -- the title of 16 BY MR. THOMAS: 17 17 this document, you would not see that. Let me read the question again. 18 18 And the histology in this two-week That would be the result of a 19 rabbit study, 2133, was consistent with all of the 19 macroscopic observation. You could only see the 20 other Prolene tissue response tests that you've 20 surface. And that's a directional information, as I gotten since 1964, correct? 21 mentioned. 21 22 22 MR. THORNBURGH: Objection. The histomorphological evaluation of 23 THE WITNESS: Yes. So if you look in 23 the implant site looks at a cross-section of the the column, inflammatory cell infiltrates only implant, top to bottom, through and through. So not associated with the mesh, for every mesh, that would only can the pathologist see the surface coating, Page 592 Page 594 be Prolene Soft mesh, Prolene mechanical cut, which but they can see all the other components through is TVT mesh, and Prolene ultrasonic cut mesh, which 2 2 the mesh implant. 3 would be a laboratory-made device to simulate a 3 Q. Okay. So which is the more valid different cutting process for TVT tape, all of the 4 observation? 5 inflammatory reactions were minimal. 5 MR. THORNBURGH: Objection. б And, further, if you look at the б THE WITNESS: The histo -- the 7 approximate average thickness of fibrous tissue, 7 histomorphological evaluation is the definitive what I would call fibrosis in studies that I've 8 read, located between the mesh fiber bundles -- and 9 BY MR. THOMAS: 10 this is measured -- attempted to be measured in 10 Okay. Sorry to jump around. microns, as we've seen in some early report --11 Going back to the Pariente study, 11 12 which was T-2260, and the Ethicon two-week rabbit pathology assessment schemes -- the results at 7 and 14 days are -- there's no distinct encapsulation for 13 study, which is T-2133, which is the better study 13 14 any product. from a preclinical perspective for Ethicon to 15 BY MR. THOMAS: 15 evaluate the safety and efficacy of its product? What does that mean, no distinct 16 I always lean towards in vivo studies 16 Q. A. 17 to simulate a patient population. 17 encapsulation? 18 A. That the fibrotic response was 18 And what value to you in preclinical Q. relatively minimal. 19 context is 2260, the Pariente study? 19 20 Let's talk about encapsulation 20 It's informational. A. quickly. I am jumping around a little bit, and I 21 Any value to you from a preclinical 21 22 perspective other than what they state? 22 apologize. 23 In questions yesterday from counsel 23 A. No. 24 in -- with respect to T-2242, the exploratory 91-day 24 Q. The next section in your disclosure tissue reaction study, there were some macroscopic 25 is the porosity section. And the porosity section

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Page 595 Page 597 for the development of mesh products only contains perspective? 2 12 entries. And counsel inquired at length about A. why you only had 12 studies to support the porosity 3 MR. THORNBURGH: Objection. 4 testing for the TVT device. BY MR. THOMAS: 5 And I think we've established pretty 5 Now, you were questioned at some clearly that T-2247, the 1973 rabbit study, is the length about why you haven't done any more porosity 7 7 first study conducted by Ethicon on Prolene mesh for studies on 6-mil Prolene mesh since the 1973 study. 8 tissue reaction, correct? 8 Why is that? 9 9 A. Yes, that's correct. Well, there's -- in preclinical 10 And we went through that study at 10 science, there are limitations on the number of Q. animal studies that can be conducted. USDA animal 11 some length. 11 12 12 welfare regulations require experimental Is the tissue reaction profile found in 2247 for Prolene mesh used in TVT consistent with 13 13 institutions to justify the use of additional the tissue reaction profile found in other Prolene animals. And part of that justification is making a 14 14 15 15 mesh marketed by Ethicon? statement that this work has not been conducted 16 16 MR. THORNBURGH: Objection. previously, and if so, then further studies are not 17 THE WITNESS: First, is that exhibit 17 allowed. 18 18 that you called out the '73 study? Q. In the 91-day rat study, T-2242, 19 BY MR. THOMAS: 19 there is an extensive section and literature 20 research -- literature search contained in the data Q. Correct. 21 A. Then the response would be that the 21 for that study. Do you recall that? 22 tissue reaction profile reported in the 1973 study A. Yes. 2.3 represents the kind of tissue reaction seen in 23 Q. And why is that literature search set 24 studies conducted since then. 24 forth in that study? 25 Including the 91-day rat study using 25 Part of the --Q. A. Page 596 Page 598 the 5 mil mesh? 1 MR. THORNBURGH: Objection. 2 Α. 2 THE WITNESS: Each research That's correct. 3 And in all of the porosity studies institution has an institutional animal care and use that are listed, the 12 that are listed here, the 4 committee whose job is to have oversight over all 5 finding of tissue reaction with respect to Prolene experimental studies and as part of that oversight, mesh, does it meet the same profile? б requires a literature search of either the public -б 7 7 well, the public and internal databases to make sure Α. Yes. 8 Q. And what is that profile? 8 that previous studies that have been conducted will 9 A relatively mild reaction, an acute not be repeated. A. phase, which is transient and passes, because the 10 BY MR. THOMAS: implant is biocompatible. The tissue reaction 11 After Ethicon obtained the results 11 transitions to a low level chronic inflammatory from the test in 2247, which is a 1973 rabbit test, reaction and a fibrotic reaction that encapsulates was there any reason to conduct further tissue 13 elements in a three-dimensional way of the mesh. reaction studies for this Prolene flat mesh? 14 14 15 And that tissue reaction is sustained 15 No. And all tissue reactions through the -- for the duration of each of the conducted on various iterations of Prolene mesh over 16 studies, and in many of those studies, there is a 17 time showed a very comparable tissue reaction as 17 18 diminution of that reaction over time. 18 described in the 1973 study. And that diminution in the reactions 19 And so the 12 studies that you site 19 20 or the change in the reactions that you've just 20 in connection with your porosity analysis all have a described is what you've described to counsel as a 21 consistent tissue reaction profile? long-term chronic reaction? 22 22 A. Yes. 23 A. That's correct. 23 Q. And is the tissue reaction profile 24 that is described in those 12 studies consistent 24 Q. And does the long-term chronic 25 reaction present any risk from a preclinical with the language in the IFU that you talked about

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at length with counsel for the plaintiff? MR. THORNBURGH: Objection. THE WITNESS: Yes, I think so. BY MR. THORNBURGH: Objection. The with counsel for the plaintiff? to provide the specifics of all clinical, preclinical, and medical testing related to all of the TVT products, and you were responding to the preclinical piece of that. Do you recall that? A. Yes, 1do. Q. So as a part of that, you gathered all of the testing that Ethicon did for each of the devices. Is that fair? A. Yes, 1do. A. That's correct. A. That's correct. Q. Okay. And you did that for the TVT a devices? A. That's correct. A. Yes. Q. You did that for the TVT-O device? A. That's correct. A. Tha		Page 599		Page 601
MR. THORNBURGH: Objection. MR. THOMAS: MR. THOMAS: Dy MR. THOMAS: Q. The next category that you were asked about -excuse me - that you were designated on is specifics of all clinical, preclinical, and medical testing related to all of the TVT products, and you were asked to be the person most showledgeable, Rule 30(b)(6) designee, for animal testing records for biocompatibility as part of the devices? A. Yes. 1do. A. Yes. 1do. A. That's correct. A. That's correct. They're all relevant. C. Q. Okay. And you did that for the TVT devices. A. That's correct. D. You did that for the TVT-O device? A. That's correct. A. Yes. D. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. And you have notebooks of all the tarm parts that were added to any of the TVT devices. You were asked to provide that in the two parts that were added to any of the TVT devices. A. That's correct. Q. And the forthe TVT-E device? A. That's correct. Q. And the the TVT-E device? A. That's correct. Q. And whave notebooks of all the tarm parts that were added to any of the TVT devices. You were asked to be the person most addeto. Correct? Q. And the extent that Ethicon of the devices of the devices of the conducted on each of those testing records for biocompatibility as a lesting records f	1	at length with counsel for the plaintiff?	1	A. Yes.
THE WITNESS: Yes, I think so. 4 BYMR. THOMAS: 5 Q. The next category that you were asked about — excuse me — that you were asked provide the specifics of all clinical, preclinical, and medical testing related to all of the TVT products, and you were responding to the preclinical piece of that. 10 Dy you recall that? 11 Do you recall that? 12 A. Yes, I do. Q. So as part of that, you gathered all of the testing that Ethicon did for each of the devices. Is that fair? 16 A. That's correct. Q. And to the extent that Ethicon all leveraged prior testing from Prolene sutures, you've also identified that? 20 A. That's correct. They're all relevant of the TVT odevices provided that for the TVT—O device? 11 A. Yes. 22 Q. Okay, And you did that for the TVT—O device? 12 Q. Okay, And you did that for the TVT—O device? 13 A. That's correct. Q. You did that for the TVT-E device? 4 A. Yes. 4 A. Yes. 5 Q. You did that for the TVT-E device? 4 A. That's correct. 9 Q. And the TVT-A device? 12 Q. And the TVT-A device? 13 Q. And the TVT-A device? 14 A. That's correct. 9 Q. And this included any new component parts that were added to any of the TVT devices. 15 Q. And you have notebooks of all the information for all of the tools that might a company those devices? 16 Q. And you have notebooks of all the tests that were conducted on each of those TVT devices there today to talk and babot the — every aspect of the conduction of any preclinical studies and testing records for bicocompatibility as part of the TVT products and states that all devices? 17 Q. And the TVT-A device? 18 Q. And the TVT-A device? 19 Q. And the TVT-C devices the parism if the tools that might a company those devices? 19 Q. And the TVT-C device the trong that a company those devices? 10 Q. And the TVT-C device the trong that a company those devices? 19 Q. And the tools that might a company those devices? 20 And the TVT-C device that for the tools that might a company those devices? 21 THE WITNESS: Yes. 22 BYMR. THOMAS: 23 Q. And,				
4 BY MR. THOMAS: 5 Q. The next category that you were asked 6 about — excuse me — that you were designated on is 8 specifies of all clinical, preclinical, and medical testing related to all of the TVT products, and you were saked to be rown were responding to the preclinical piece of that. 11 Do you recall that? 2 A. Yes, Ido. 3 Q. So as a part of that, you gathered all of the testing that Ethicon did for each of the devices. Is that fair? 4 all of the testing that Ethicon did for each of the devices. Is that fair? 5 A. That's correct. 6 A. That's correct. They're all relevant. 7 Q. Okay. And you did that for the TVT device. Yes, Q. You did that for the TVT-O device? 8 A. That's correct. 9 Q. You did that for the TVT-O device? 9 A. That's correct. 9 Q. You did that for the TVT-E device? 4 A. Yes. 1 Q. And the TYT-A device? 4 A. Yes, Q. You did that for the TVT-E device? 5 A. That's correct. 9 Q. And the TYT-A device? 4 A. Yes, Q. And you have notebooks of all the parts that were added to any of the TVT devices. 1 You were asked to per maiked to the the person most and you were asked to be the person most workedgeable, Rule 30(b)(6) designe, for animal testing records for biocompatibility as part of the design of the product. Correct? 1 Q. Okay. And you did that for the TVT devices. 2 Q. Okay. And you did that for the TVT-O device? 2 A. Yes, C. Which is called animal testing records for biocompatibility as a part of the TVT devices. By Mr. THOMAS: Page 600 1 A. That's correct. 9 Q. And the TVT-A device? 4 A. Yes, C. Which is called animal testing records for biocompatibility as part of the TVT devices. Page 602 1 Q. And the texten that Ethicon less for the person most knowledgeable, Rule 30(b)(6) designe, for animal testing records for biocompatibility as a bart of the TVT devices. Page 600 1 Q. Nay, THOMAS: 1 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and restring regarding your TVT products and states that all documents responsive to this category share al				
5 Q. The next category that you were asked b about — excuse me — that you were designated on is 7 Section BB. And you were asked to provide the 8 specifies of all clinical, preclinical, and medical 1 testing related to all of the TVT products, and you were responding to the preclinical piece of that. 1 Do you recall that?		·		
6 about excuse me that you were designated on is specifics of all clinical, preclinical, and medical specifics of all clinical, preclinical, and medical were responding to the preclinical, and medical to testing related to all of the TVT products, and you were asked to be the person most nowledgeable, Rule 30(h)(6) designee, for animal testing records for biocompatibility as part of the devices. It hat fair? 12 A. Yes, I do. 3 Q. So as a part of that, you gathered devices. Is that fair? 4 all of the testing that Ethicon did for each of the devices. Is that fair? 5 Q. And to the extent that Ethicon leveraged prior testing from Prolene sutures, you've also identified that? 6 A. That's correct. 7 Q. And you're prepared today to talk about the TVT evant. 8 page 600 8 A. That's correct. 9 Q. You did that for the TVT-O device? 1 A. That's correct. 2 Q. You did that for the TVT-Secur 3 device? 4 A. Yes. 5 Q. You did that for the TVT-Secur 4 A. That's correct. 5 Q. You did that for the TVT-E device? 6 A. That's correct. 6 A. That's correct. 7 Q. And the TVT-A device? 8 A. That's correct. 9 Q. You did that for the TVT-E device? 9 A. That's correct. 1 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 1 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 1 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 2 Q. And up have notebooks of all the testing troub to talk about the every aspect of the conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the T			5	
7 Section BB. And you were asked to provide the specifics of all chinical, preclinical, and medical testing related to all of the TVT products, and you were responding to the preclinical piece of that. 1 Do you recall that? 1 A. Yes, I do. 2 A. Yes, I do. 3 Q. So as a part of that, you gathered that all of the testing that Ethicon did for each of the devices. Is that fair? 1 A. That's correct. 2 A. That's correct. 3 device, correct? 4 A. Yes. 4 A. Yes, I do. 2 Q. And to the extent that Ethicon elidentified that? 4 A. That's correct. 5 Q. You did that for the TVT—O device? 5 Q. You did that for the TVT—O device? 6 A. That's correct. 7 Q. And the rother TVT—O device? 8 A. That's correct. 9 You were asked to be the person most the design of the product. Correct? 4 A. Yes. 9 Q. And upon the extent that Ethicon did for each of the design of the product. Correct? 4 A. Yes. 9 Q. And upon the extent that Ethicon did for each of the design of the product. 9 Q. And you're prepared today to talk about all of these 64 documents concerning the animal testing records for biocompatibility as a late of the TVT foducts? 1 A. That's correct. 1 Yes. 1 Yes. 1 Yes. 2 Q. Okay. And you did that for the TVT—O device? 2 MR. THOMAS: 2 Q. You did that for the TVT—O device? 3 device. 4 A. Yes. 2 Page 600 1 A. That's correct. 4 A. Yes. 2 Page 600 2 Q. You did that for the TVT—E device? 5 Q. You did that for the TVT—E device? 6 A. That's correct. 9 Q. And the TVT—A device? 1 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 3 A. That's correct. 4 A. That's correct. 5 Q. And you have notebooks of all the testing records for biocompatibility as part of the design of the product. 2 D. MR. THOMAS: 2 D. A. That's correct. 3 device, correct? 4 A. Yes. 4 A. That's correct. 5 Q. You did that for the TVT—E device? 6 A. That's correct. 9 Q. And the TVT—A device? 1 A. That's correct. 1 You were asked to be the person most lead of 4 different documents responsive to this called any pr				
8 specifies of all clinical, preclinical, and medical were responding to the TVT products, and you were responding to the preclinical piece of that. 11 Do you recall that? 12 A. Yes., I do Q. So as a part of that, you gathered all of the testing that Ethicon did for each of the devices. Is that fair? 15 devices. Is that fair? 16 A. That's correct. 17 Q. And to the extent that Ethicon leveraged prior testing from Prolene sutures, you've also identified that? 18 leveraged prior testing from Prolene sutures, you've also identified that? 19 Q. And to the extent that Ethicon leveraged prior testing from Prolene sutures, you've also identified that? 20 A. That's correct. They're all relevant. 21 relevant. 22 Q. Okay. And you did that for the TVT 22 device, correct? 23 device, correct? 24 A. Yes. 25 Q. You did that for the TVT-O device? 26 Q. You did that for the TVT-O device? 27 Q. You did that for the TVT-Secur 28 device? 29 Q. You did that for the TVT-E device? 30 device? 40 A. That's correct. 41 A. That's correct. 42 A. Yes. 43 A. Yes. 44 A. Yes. 45 Q. And the TVT-Medvice? 46 A. That's correct. 47 Q. And the included any new component information for all of the tools that might accompany those devices? 48 A. That's correct. 49 Q. And this included any new component information for all of the tools that might accompany those devices? 40 A. That's correct. 41 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 40 A. That's correct. 41 A. That's correct. 42 A. Yes. 43 A. Yes. 44 A. Yes. 45 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing records for biocompatibility as part of the vocation of the person of the following control that information for all of the tools that might accompany those devices? 45 A. That's correct. 46 A. That's correct. 47 Q. And this included any new component information for all of the tools that might accompany those devices? 48 A.			7	
testing related to all of the TVT products, and you were responding to the preclinical piece of that. Do you recall that? A. Yes, Ido. So So as a part of that, you gathered all of the testing that Ethicon did for each of the devices. Is that fair? A. That's correct. A. That's correct. A. That's correct. They're all all everaged prior testing from Prolene sutures, you've also identified that? Q. And to the extent that Ethicon are you've also identified that? A. That's correct. They're all are relevant. Page 600 A. That's correct. They're all are relevant. Page 600 A. That's correct. Q. You did that for the TVT-O device? A. Yes. Q. You did that for the TVT-O device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. And this included any new component parts that were added to any of the TVT devices. Q. And this included any new component parts that were added to any of the TVT devices. Q. And this included any new component parts that were added to any of the TVT devices. Q. And this included any new component of the resting that Ethicon did for each of those TVT devices here today to talk about the every aspect of the product. Correct? A. Yes. Q. And hore you have listed 64 different documents concerning the about all of these 64 documents on a minal testing records for biocompatibility as part of the TVT products. A. Yes. Q. Now, Category Dasks for the per				
10 were responding to the preclinical piece of that. 10 Do you recall that? 11 Do you recall that? 12 A. Yes. 4 A. Yes. 4 A. Yes. 4 A. That's correct. 15 A. That's correct. 16 A. That's correct. 17 A. That's correct. 18 weraged prior testing from Prolene sutures, you've a last identified that? 18 weraged prior testing from Prolene sutures, you've also identified that? 19 A. That's correct. 19 A. That's correct. 19 A. That's correct. 19 A. That's correct. 19 A. Yes. 19 A. That's correct. 10 A. That's correct. 10 A. That's correct. 10 A. That's correct. 10 A. That's correct. 11 A. That's correct. 12 A. Yes. 12 A. Yes. 13 A. Yes. 14 A. Yes. 15 A. That's correct. 16 A. That's correct. 17 A. That's correct. 18 A. That's correct. 19 A. That's correct. 10 A. That's correct. 10 A. That's correct. 11 A. That's correct. 12 A. That's correct. 13 A. That's correct. 14 A. That's correct. 15 A. That's correct. 16 A. That's correct. 17 A. That's correct. 18 A. That's correct. 19 A. That's correct. 19 A. That's correct. 10 A. That's correct. 11 A. That's correct. 12 A. That's correct. 13 A. That's correct. 14 A. That's correct. 15 A. That's correct. 16 A. That's correct. 17 A. That's correct. 18 A. That's correct. 19 A. That's correct. 19 A. That's correct. 10 A. That's correct. 11 A. That's correct. 12 A. That's correct. 13 A. That's correct. 14 A. That's correct. 15 A. That's correct. 16 A. That's correct. 17 A. That's correct. 18 A. That's correct. 19 A. That's correct. 19 A. That's correct. 10 A. That's correct. 10 A. That's correct. 11 A. That's correct. 12 A. That's correct. 13 A. That's correct. 14 A. Tha		*		
11				
12 A. Yes, Ido. 12 Q. And here you have listed 64 different 13 documents, correct?			11	
Q. So as a part of that, you gathered devices. Is that fair? A. That's correct. Q. And to the extent that Ethicon lasso identified that? Q. And to the extent that Ethicon lasso identified that? Q. And to the extent that Ethicon lasso identified that? Q. And you're prepared today to talk about all of these 64 documents concerning the animal testing records for biocompatibility as a part of the TVT products? A. That's correct. They're all Q. A. That's correct. They're all Q. Okay. And you did that for the TVT A. Yes. Q. You did that for the TVT-O device? Q. You did that for the TVT-O device? Page 600 Page 600 Page 602 A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. And the TVT-A device? A. That's correct. Q. And the statewer added to any of the TVT devices. You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? A. That's correct. Q. And you're prepared today to talk about the — every aspect of the TVT products? A. That's correct. Q. Ox You did that for the TVT-Ox device. A. That's correct. Q. And you're prepared today to talk about the — every aspect of the TVT products. A. That's correct. Q. And you're prepared today to talk about the — every aspect of the TVT products. A. That's correct. Q. You did that for the TVT-Ox devices. You were asked by the plaintiffs to provide that accompany those devices? A. That's correct. Q. And you're prepared today to talk about the — every aspect of the TVT products. A. That's correct. Q. And you're prepared today to talk about the — every aspect of the TVT products. A. That's correct. Q. The next category is one that we substance of any and all studies, data, and/or other evidence that	12		12	
14 all of the testing that Ethicon did for each of the devices. Is that fair? 15 Q. And you're prepared today to talk about all of these 64 documents concerning the about all of these 64 documents concerning the animal testing records for biocompatibility as a part of the TVT products? 17 Q. And to the extent that Ethicon 16 about all of these 64 documents concerning the animal testing records for biocompatibility as a part of the TVT products? 19 also identified that? 20 A. That's correct. They're all 20 MR. THORNBURGH: Dave, what section are you or? 21 relevant. 21 device, correct? 22 MR. THOMAS: CC, which is called animal testing records for biocompatibility as part of the design of this product. 25 Q. You did that for the TVT-O device? 25 BY MR. THOMAS: 2 Q. You did that for the TVT-Secur 26 Wrow, and you did that for the TVT-Secur 27 MR. THOMAS: 2 Q. You did that for the TVT-Secur 28 MR. THOMAS: 29 MR. THOMAS: 3 device? 4 A. Yes. 4 regarding your TVT products and states that all documents responsive to this category have already documents responsive to this category, and you have those here with you today? 4 A. That's correct. 7 A. That's correct. 8 have just been through are responsive to this category, and you have those here with you today? 6 A. That's correct. 10 Q. Category EE says the		·	13	= -
15 devices. Is that fair? 16 A. That's correct. 16 A. That's correct. 17 Q. And to the extent that Ethicon 18 leveraged prior testing from Prolene sutures, you've 18 lass identified that? 19 also identified that? 19 also identified that? 19 A. That's correct. They're all 19 also identified that? 19 A. That's correct. They're all 19 are you on? 10 A. That's correct. 10 A. That's correct. 10 A. That's correct. 10 A. That's correct. 11 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing equivate and testing vour TVT products? 10 A. That's correct. 11 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products. 10 A. That's correct. 11 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products. 11 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products. 11 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products. 10 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing records for biocompatibility as part of the design of this product. 12 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies. In the transport of the device? 12 Q. Now Qu did that for the TVT-E device? 13 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies. 13	14		14	
16 A. That's correct. 17 Q. And to the extent that Ethicon 18 leveraged prior testing from Prolene sutures, you've 19 also identified that? 20 A. That's correct. They're all 21 relevant. 22 Q. Okay. And you did that for the TVT 23 device, correct? 24 A. Yes. 25 Q. You did that for the TVT-O device? 26 Q. You did that for the TVT-O device? 27 Q. You did that for the TVT-Secur 28 device? 29 Q. You did that for the TVT-Secur 29 Q. You did that for the TVT-Secur 20 Q. You did that for the TVT-E device? 21 A. That's correct. 22 Q. You did that for the TVT-E device? 23 device? 4 A. Yes. 5 Q. You did that for the TVT-E device? 4 A. Yes. 6 A. That's correct. 7 Q. And the TVT-A device? 8 A. That's correct. 9 Q. And the TVT-A device? 10 parts that were added to any of the TVT devices. 11 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 10 Q. And you have notebooks of all the tests that were conducted on each of those TVT devices of the — any new components to any of the TVT devices. 11 devices? 12 MR. THONAS: 13 device? 14 A. That's correct. 15 Q. You did that for the TVT-E device? 16 A. That's correct. 17 Q. And the TVT-A device? 18 A. That's correct. 19 Q. And the TVT-A device? 10 Darks that were added to any of the TVT devices. 11 Q. Category Et says the development and coordination of any preclinical studies. And to the extent that you have studies responsive to this category, and you have those here with you today? 19 devices here today to talk about the — every aspect of the — any new components to any of the TVT devices of the — any new components to any of the TVT devices of the — any new components to any of the TVT devices of the — any new components to any of the TVT devices of the — any new components to any of the TVT devices of the output that the device of the many new components to any of the TVT devices of the output that the device of the many new components to any of the TVT devices of the output that the device of the many new compon			15	
17 New regard prior testing from Prolene sutures, you've also identified that? 18 part of the TVT products? 18 part of the TVT products? 19 A. Yes. 20 MR. THORNBURGH: Dave, what section are you on? 21 are you on? 22 MR. THOMAS: CC, which is called animal testing records for biocompatibility as part of the TVT products? 24 A. Yes. 24 of the design of this product. 25 BY MR. THOMAS: 26 MR. THORNBURGH: Dave, what section are you on? 27 MR. THOMAS: CC, which is called animal testing records for biocompatibility as part of the design of this product. 25 BY MR. THOMAS: 24 of the design of this product. 25 BY MR. THOMAS: 26 MR. THORNBURGH: Dave, what section are you on? 27 MR. THOMAS: 28 MR. THOMAS: 29 MR. THOMAS:	16	A. That's correct.	16	
leveraged prior testing from Prolene sutures, you've also identified that? A. That's correct. They're all 22 Q. Okay. And you did that for the TVT 23 device, correct? A. Yes. D. You did that for the TVT-O device? Page 600 1 A. That's correct. Q. You did that for the TVT-Secur A. Yes. Q. You did that for the TVT-Secur A. Yes. Q. You did that for the TVT-E device? A. Yes. Q. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. C. And the TVT-A device? A. That's correct. A. That's correct. A. That's correct. C. And this included any new component parts that were added to any of the TVT devices. You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? A. That's correct. Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT' devices here today to talk about the every aspect of the any new components to any of the TVT' devices here today to talk about the every aspect of the any new components to any of the TVT' devices have developed and testing regarding your TVT products. A. That's correct. Q. And you have notebooks of all the tests that were conducted on each of those TVT devices have been identified in previous categories as well, and they're here with you today? A. That's correct. Q. The next cate	17	Q. And to the extent that Ethicon	17	animal testing records for biocompatibility as a
also identified that? A. That's correct. They're all celevant. 22 Q. Okay. And you did that for the TVT device, correct? A. Yes. Q. You did that for the TVT-O device? Page 600 1 A. That's correct. Q. You did that for the TVT-Secur device? A. Yes. Page 600 1 A. That's correct. Q. You did that for the TVT-Secur device? A. Yes. Page 600 1 A. That's correct. Q. You did that for the TVT-Secur device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. And the statewer added to any of the TVT devices. You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? A. That's correct. Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices? MR. THORNBURGH: Dave, what section are you on? AMR. THOMAS: CC, which is called animal testing records for biocompatibility as part of the design of this product. BY MR. THOMAS: Page 600 Page 602 A. That's correct. A. Yes. BY MR. THOMAS: Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products and states that all documents responsive to this category have already been identified. A. That's correct. A. That's correct. A. That's correct. Q. And the statement is that an inmal the very and all studies. And to the extent that you have studies responsive to this category, those have been identified in previous category, those have been identified in previous categories as well, and they're here with you today? A. That's correct. Q. The next category is one that we spent a good deal of time on. Next category deals with the identity of, the location of, and the system correct and you have those here of any and all studies, data, and/or other evidence that	18	leveraged prior testing from Prolene sutures, you've	18	
21 relevant. 22 Q. Okay. And you did that for the TVT 23 device, correct? 24 A. Yes. 25 Q. You did that for the TVT-O device? 26 Q. You did that for the TVT-Secur 27 Q. You did that for the TVT-Secur 28 A. That's correct. 29 Q. You did that for the TVT-Secur 30 device? 4 A. Yes. 5 Q. You did that for the TVT-E device? 4 A. Yes. 6 A. That's correct. 7 Q. And the TVT-A device? 8 A. That's correct. 9 Q. And the TVT-A device? 10 parts that were added to any of the TVT devices. 11 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 10 Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices. 11 You were skeen the two today to talk about the every aspect of the any new components to any of the TVT devices. 12 Q. MR. THOMAS: 13 are you on? 14 MR. THOMAS: 15 Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products and states that all documents responsive to this category have already been identified. 15 Q. And this included any new component and coordination of any preclinical studies. And to the extent that you have those here with you today? 10 A. That's correct. 11 Q. Category EE says the development and coordination of any preclinical studies. And to the extent that you have been identified in previous category, those have been identified in previous categories as well, and they're here with you today? 11 A. That's correct. 12 Q. The next category is one that we spent a good deal of time on. Next category deals with the identity of, the location of, and the substance of any and all studies, data, and/or other evidence that form the basis of the following claim/statement included in the attached instructions for use for the TVT products. 11 And the statement is that animal	19		19	A. Yes.
22 Q. Okay. And you did that for the TVT 23 device, correct? 24 A. Yes. 25 Q. You did that for the TVT-O device? 26 Page 600 Page 600 Page 600 Page 602 1 A. That's correct. 2 Q. You did that for the TVT-Secur 3 device? 4 A. Yes. 5 Q. You did that for the TVT-Secur 4 A. Yes. 6 A. That's correct. 7 Q. And the TVT-A device? 8 A. That's correct. 9 Q. And this included any new component parts that were added to any of the TVT devices. 11 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 4 A. That's correct. 9 Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices. 18 of the any new components to any of the TVT devices. 19 Q. And good have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices. 19 Q. And, also, as a part of this, you and the vertical part of the documents that were added to any new component to any of the TVT devices. 10 A. That's correct. 11 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 10 A. That's correct. 11 Q. Category EE says the development and coordination of any preclinical studies. And to the extent that you have studies responsive to this category, those have been identified in previous categories as well, and they're here with you today? 10 A. That's correct. 11 Q. The next category is one that we spent a good deal of time on. Next category deals with the identity of, the location of, and the substance of any and all studies, data, and/or other evidence that form the basis of the following claim/statement is cluded in the attached instructions for use for the TVT products. And the statement is that animal	20	A. That's correct. They're all	20	MR. THORNBURGH: Dave, what section
23 device, correct? 24 A. Yes. 25 Q. You did that for the TVT-O device? Page 600 Page 602 And Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing records for biocompatibility risk assessments for each 600 Page 600 Page 600 Page 600 Page 600 Page 600 Page 602 A. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products and states that all documents responsive to this category, and you have those here with you today? and they in the factor of any preclin	21	relevant.	21	are you on?
A. Yes. Q. You did that for the TVT-O device? Page 600 Page 602 A. That's correct. Q. You did that for the TVT-Secur device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. You did that for the TVT-E device? A. That's correct. Q. And the TVT-A device? A. That's correct. Q. And the statement is that were added to any of the TVT devices. Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the design of this product. BY MR. THORNBURGH: Objection. THE WITNESS: Yes. Q. And, also, as a part of this, you Page 602 Page and psoult regarding sout	22	Q. Okay. And you did that for the TVT	22	
Page 600 Page 602	23	device, correct?	23	animal testing records for biocompatibility as part
Page 600 1 A. That's correct. 2 Q. You did that for the TVT-Secur 3 device? 4 A. Yes. 5 Q. You did that for the TVT-E device? 6 A. That's correct. 7 Q. And the TVT-A device? 8 A. That's correct. 9 Q. And this included any new component parts that were added to any of the TVT devices. 11 You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? 4 A. That's correct. 5 Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices. 20 MR. THORNBURGH: Objection. 21 THE WITNESS: Yes. 22 BY MR. THOMAS: 23 Q. And, also, as a part of this, you 24 have biocompatibility risk assessments for each of	24	A. Yes.	24	of the design of this product.
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25 these devices. Isn't there? 25 studies show that implementation of Prolene mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's correct. Q. You did that for the TVT-Secur device? A. Yes. Q. You did that for the TVT-E device? A. That's correct. Q. And the TVT-A device? A. That's correct. Q. And this included any new component parts that were added to any of the TVT devices. You were asked by the plaintiffs to provide that information for all of the tools that might accompany those devices? A. That's correct. Q. And you have notebooks of all the tests that were conducted on each of those TVT devices here today to talk about the every aspect of the any new components to any of the TVT devices? MR. THORNBURGH: Objection. THE WITNESS: Yes. BY MR. THOMAS: Q. And, also, as a part of this, you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Now, Category DD asks for the person most knowledgeable concerning the evaluation of data and results of any preclinical studies and testing regarding your TVT products and states that all documents responsive to this category have already been identified. And so all of the documents that we have just been through are responsive to this category, and you have those here with you today? A. That's correct. Q. Category EE says the development and coordination of any preclinical studies. And to the extent that you have studies responsive to this category, those have been identified in previous categories as well, and they're here with you today? A. That's correct. Q. The next category is one that we spent a good deal of time on. Next category deals with the identity of, the location of, and the substance of any and all studies, data, and/or other evidence that form the basis of the following claim/statement included in the attached instructions for use for the TVT products.
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Page 603 Page 605 elicits a minimal inflammatory reaction in tissues, 1 suture NDA, correct? 2 which is transient and is followed by the deposition MR. THORNBURGH: Objection. 3 of a thin, fibrous layer or tissue which can grow 3 THE WITNESS: Yes, that's correct. through the interstices of the mesh, thus 4 4 BY MR. THOMAS: 5 5 incorporating the mesh to adjacent tissue. And that was based upon the studies, O. 6 Your first tab is 1964. Why do you one through five, that appear under this section of 7 include information from 1964 in the materials that 7 the disclosure? 8 you designate in response to this category? 8 A. Yes, that's correct. Long-term 9 As -- as we discussed earlier --9 implantation studies and long-term retention of 10 10 MR. THORNBURGH: Objection. breaking strength. THE WITNESS: -- the Prolene 11 11 Now, if you go to Tab 6, the Miller 12 polypropylene suture forms the basis for the Prolene 12 study, what did you learn about the -- the issue of polypropylene mesh, the same Prolene polypropylene 13 tissue enzymes in the advent of polypropylene 13 14 filament. 14 sutures? 15 And so any studies that are relevant 15 A. This is a paper in the open to the tissue reaction of suture are relevant in a 16 16 literature. We can look at it in detail if we need way to the filaments that comprise Prolene to, which, as you say, is Tab 6. polypropylene mesh. 18 But I recall there's some language in 18 BY MR. THOMAS: 19 19 there that talks about the Prolene polypropylene 20 O. And the tissue reaction studies that 20 suture is resistant to the effects of tissue 21 21 were part of the NDA were reviewed by FDA in the NDA enzymes. 22 22 approval process, correct? Q. And what was it about other sutures 23 A. That's correct. 23 in use at the time that created a risk of 24 0. And FDA ultimately approved the use degradation from tissue enzymes? of the Prolene suture for sale in the United States 25 Yeah, this is very significant, Page 604 Page 606 under the new drug application? because at the time, another monofilament suture, as 2 That's correct. 2 Prolene suture, was catgut suture, and that was made Α. 3 MR. THORNBURGH: Objection. 3 of intestinal collagen from animals, and it's known 4 BY MR. THOMAS: 4 to degrade over time. 5 And FDA ultimately approved the 5 So to have a suture that doesn't 6 language that appears up above in the IFU in degrade in the presence of tissue enzymes, whether б 7 7 substance for the Prolene suture? it's placed in the stomach or part of an 8 MR. THORNBURGH: Objection. 8 inflammatory process or it's in the pancreas, that's 9 THE WITNESS: That's correct. 9 something that would be new to many surgeons. BY MR. THOMAS: 10 Now, you talked at length about the 10 11 And the 44 documents that you cite 11 fact that molecular weight and tensile strength are below this category, are all of these consistent 12 the two key components for you in preclinical to 12 with the language that appears in the IFU on which 13 evaluate the extent to which degradation is a 13 you're designated? 14 14 significant event, correct? 15 A. Yes. 15 A. Absolutely. 16 Q. Now, the next category says the 16 Q. In any of the 59 -- excuse me -- 49 papers, from 1964 to 2013, did you identify any material is not absorbed, nor is it subject to 17 17 18 degradation or weakening by the action of tissue 18 Prolene suture or mesh that underwent degradation in the form of change in molecular weight or loss of 19 enzymes. 19 20 Now, this language was also part of 20 tensile strength that caused you concern from a preclinical perspective? 21 the original instruction for use for the 21 22 polypropylene -- excuse me -- the Prolene suture? 22 MR. THORNBURGH: I just want to 23 A. That's correct. 23 object to the representation that even molecular 24 And this language was specifically 24 weight studies were even done in the 40 or so --25 approved by the FDA in its approval of the Prolene 25 40 -- however many studies that are in this list.

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Page 607 Page 609 1 Yes. 1 Are you representing to the Court A. 2 that molecular weight studies were done in each one As a pathologist reviewing the data 3 3 of these tests? that's been provided to you, are you able to review 4 MR. THOMAS: No, I'm not. I am 4 that data and determine the extent to which those 5 5 various grading scales can be analyzed to reach a asking --6 common result? 6 MR. THORNBURGH: Objection. Move to 7 7 strike. A. Yes. 8 That's a representation that you've 8 Q. And tell me how you do that. 9 9 been making to this jury this entire time. Well, you look --10 MR. THOMAS: Please. No speeches to 10 MR. THORNBURGH: Objection. I don't the jury. That's not appropriate. You know that. 11 11 even understand the question. 12 MR. THORNBURGH: It's fair BY MR. THOMAS: 12 13 13 representation, honest ones. Q. You can answer the question. 14 14 BY MR. THOMAS: A. Answer the question? 15 Dr. Barbolt, with respect to the 49 15 You look at the individual Q. documents that you've identified in response to this 16 observations from each of the studies and you make a 16 issue of the materials not absorbed, nor is it judgment based on the description and the severity 17 18 subject to degradation or weakening by the action of 18 scores that might be associated with that 19 tissue enzymes, did you find any information in any 19 observation about what really happened. 20 form that caused you concern that there was 20 So for me to go back and look at a 21 21 degradation from a preclinical perspective that study conducted under the Sewell scheme that we 22 22 caused you concern? talked about yesterday, I could reinterpret those MR. THORNBURGH: Objection. 23 23 results in a manner that I would have recorded the 24 THE WITNESS: No. result if I were going to be doing that work today. 25 BY MR. THOMAS: 25 It takes some work, and it needs to Page 608 Page 610 Category 4 is the person most be done by a person trained in histomorphological 2 knowledgeable regarding a 28-day intramuscular 2 evaluation, but it's not a difficult task. 3 reaction study. 3 Why do pathologists record in detail 4 We already talked about that. That's 4 what they observe? 5 the study that you did after the positive 5 That forms the basis for their cytotoxicity study in the Ulmsten device where you б interpretation of the study results. б 7 then did the intramuscular study to determine the 7 And does that allow someone to come Q. 8 extent to which the TVT was going to be cytotoxic in 8 behind them to analyze the extent to which they 9 vivo. 9 agree with those findings? 10 Absolutely. And the -- and the --10 A. That's correct. 11 Q. And that result was negative? 11 and the safety mechanism for that is the fact that 12 Α. That's correct. There was no 12 the slides are considered the ultimate raw data in a evidence of in vivo cytotoxicity. 13 pathology study. 13 14 Q. And you were the person who ran that 14 This allows another pathologist to go 15 test? 15 behind the study pathologist and re-read those Yes. I was the study director and slides to generate their own set of data and their 16 A. 16 17 own conclusions to see how they compare with the 17 study pathologist. 18 Q. And you're prepared to talk about 18 original study pathologist. It's done very 19 that test today? commonly. 19 20 A. Yes. 20 And is that the reason why you try to Q. 21 In questioning yesterday, you were 21 preserve slides where you can of these kinds of 22 shown a variety of grading scales used by 22 studies? pathologists over the years to evaluate tissue 23 Yes. Yes. Every intention is to response from various implantation studies. Do you 24 maintain raw data as long as possible. 25 recall that? 25 Now, you talked before in the 91-day

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Page 611 Page 613 study, T-2242, you were the pathologist who reviewed which the study pathologist believes reflects the 2 2 those slides, correct? microslides. 3 3 A. That's correct. Q. In your training, education, and 4 4 Q. And you talked about how you may have experience in your area of expertise, do 5 either recorded the data on an Excel spreadsheet or 5 histologists keep the notes that they initially make 6 perhaps made notes before you made your final when they ultimately record their findings in their 7 7 report; is that right? final report? 8 A. That's correct. 8 A. No. 9 9 And I think you also said that you MR. THORNBURGH: Objection. 10 didn't retain any of the notes that you might have 10 Are you talking about histologists kept on your initial findings that were later 11 that have a litigation hold in place? 11 recorded in the document which is 2242. Is that 12 12 THE WITNESS: It wouldn't matter to 13 fair? 13 me. 14 14 A. That's correct. MR. THOMAS: In 2000, the year, 2000. 15 Q. Is that common? 15 MR. THORNBURGH: It wouldn't matter 16 That's standard industry practice. 16 to you? A. 17 Tell me what you mean by "standard 17 MR. THOMAS: Let's take a break. Q. 18 THE VIDEOGRAPHER: Going off the 18 industry practice." 19 A. Well, pathologists have an 19 video record at 6:23. 20 opportunity to go back to the original data, that's 20 This concludes Tape Number 5, 21 21 the slide, this week, next week, some other Volume 2 in the videotape deposition of Dr. 22 period -- point in time. Thomas A. Barbolt. 22 2.3 23 Many times studies occur over a long (Short break.) 24 period of time, and a pathologist may be involved in 24 THE VIDEOGRAPHER: We're back on the 25 a lot of different studies. So at the end of a long 25 video record. It's 6:34. Page 612 Page 614 period of time, a study pathologist may want to go 1 This begins Tape Number 6, Volume 2 2 back and revisit the original observations from the of the videotape deposition of Dr. Thomas A. 3 first look. 3 Barbolt. 4 4 BY MR. THOMAS: And maybe something that's -- that is 5 observed at a later time point now causes the Dr. Barbolt, in response to an pathologist to reevaluate those earlier slides. б objection from Mr. Thornburgh, you volunteered it б 7 There could be many iterations of slide evaluation. 7 wouldn't matter to you if there was a litigation 8 But when I say it's standard industry 8 hold in place about whether you keep notes. practice, it's the signed individual animal 9 Have you ever destroyed any documents observations that becomes the raw data for the study 10 or discarded any documents that you knew were 10 11 report. 11 subject to a litigation hold in this case? MR. THORNBURGH: Objection; asked and 12 12 Q. Okay. Why are your notes not raw data? 13 13 answered. 14 A. Because they can change over time. 14 THE WITNESS: No. 15 Q. Okay. And what is raw data to a 15 BY MR. THOMAS: pathologist insofar as the histology report goes? 16 You were asked a number of questions 16 17 about preclinical tests and symptoms of delayed 17 A. The slides. 18 O. And what significance is the report 18 wound healing, ulceration, and increased that the pathologist -- the pathologist makes in the 19 inflammation. 19 20 study? 20 Of the studies that we have just been 21 21 A. through in great detail, did you see any evidence of I don't understand the question. 22 Q. Okay. What does the histology report 22 delayed wound healing in the tissue integration 23 represent insofar as your review of the slides? 23 studies that you reviewed that you would attribute It represents the raw data signed off 24 to Prolene mesh? 24 MR. THORNBURGH: Objection. 25 25 by the study pathologist. And that's the results

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Page 615 Page 617 THE WITNESS: No. degradation, were you able to identify in any of the 1 BY MR. THOMAS: numerous studies that we've just identified any 3 increased inflammation that you were able to Well, same question for Prolene 4 sutures. 4 attribute to Prolene mesh? 5 5 No. A. No. A. 6 6 (Document marked for identification Q. In all of the studies that we've just 7 7 as Exhibit T-2263.) described in some detail, were you able to find any 8 evidence of ulceration in those animal studies that 8 BY MR. THOMAS: 9 you would attribute to Prolene mesh? 9 Let me show you what I've marked as 10 A. No. 10 Deposition Exhibit 2263. 2263 is the binder that you prepared 11 11 Were you able to find any evidence of 12 ulceration due to Prolene suture in those studies we 12 for the seven-year dog study. Do you see that? just described? 13 13 A. 14 14 A. Q. And the seven-year dog study is what 15 Q. And, finally, of all of the studies 15 counsel asked you many questions about I guess that we just went through in great length, did you earlier today. Is that fair? 16 16 find any increased inflammatory response that you 17 17 Α. Yes. were able to attribute to any leachables from 18 18 And I want to go through that study 19 Prolene suture? 19 with you a little bit. 20 MR. THORNBURGH: Objection. 20 I'll represent to you that this 21 document has in it a number of documents that hadn't 21 THE WITNESS: No. 22 BY MR. THOMAS: been marked, and that's why I marked it all 22 23 Were you able to find any increased 23 together. And just because it's going to be 24 inflammatory response that you were able to easier -- and I'll try to save time -- I'm going to attribute to leachables from Prolene mesh? mark the final report separately, because I can't Page 616 Page 618 1 A. No. put my hands on it very quickly, and I don't want to 2 Were you able to find any increased keep you here any longer than I have to. Q. inflammation that you were able to attribute to 3 3 (Document marked for identification particle loss for Prolene suture? 4 as Exhibit T-2264.) 5 5 MR. THOMAS: I'll mark 2264 the same A. 6 report that we marked earlier today. This didn't б Q. Were you able to find any increased 7 7 inflammation that you were able to attribute to have the folded back front page. 8 Counsel, it's 2264. particle loss from Prolene mesh? 9 A. 9 BY MR. THOMAS: MR. THORNBURGH: Objection. 10 Exhibit 2264 is the October 15, 1992 10 BY MR. THOMAS: 11 report that says: Seven-year data for ten-year 11 12 Prolene. Do you recall that? Were you able to find in all of those 12 13 studies that we've just discussed any instance of 13 A. Yes. delayed wound healing that you were able to 14 14 Q. And you were asked a number of attribute to degradation of Prolene suture? 15 questions earlier about this document concerning the 15 A. scanning electron microscopy conducted at that time. 16 How about any degradation of Prolene Q. 17 Do you recall that? 17 18 mesh? 18 A. Yes. 19 19 And you identified in the report Α. 20 With respect to ulceration, were you where someone observed cracks on the surface of some able to find evidence in any of the studies that 21 Prolene mesh. Fair? we've just identified any ulceration that you were 22 Α. Yes. 22 23 23 able to attribute the degradation of Prolene mesh? O. Dr. Barbolt, when does a surface A. 24 crack in Prolene mesh raise preclinical issues that 24 25 need to be investigated further? 25 Q. And, likewise, with respect to

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Page 619 Page 621 1 A. 1 A. When there's a loss in tensile A change in molecular weight is --2 strength. I think that's the -- that would be MR. THORNBURGH: Same objection. I'm 3 the -- the final straw. There might be impact on sorry. molecular weight, but if there was no impact on 4 THE WITNESS: -- is a quantitative 5 tensile strength, that would be the -- that would be 5 measure. That would suggest it's quite reliable. 6 the -- the definitive endpoint. 6 And it would be a measure of degradation of the 7 7 Why are surface cracks alone, without polymer. 8 any evidence of tensile strength issues or molecular 8 BY MR. THOMAS: 9 9 weight, why don't they raise preclinical issues for And what is tensile strength? 10 you? 10 Tensile strength is the force A. 11 11 MR. THORNBURGH: Objection. required to break a fiber, in a -- in a brief 12 THE WITNESS: Because they don't have 12 description. 13 13 an impact on molecular weight, which would be Q. And why is a loss of tensile strength evidence of degradation of polymer chains. And if 14 14 important to you as a preclinician? 15 there were degradation of polymer chains, that would 15 Tensile strength is a measure of fiber integrity. It's a measure of presence or be reflected in a loss in tensile strength. 16 16 17 So those two endpoints are key absence of degradation. preclinical endpoints. Other endpoints are 18 18 And for suture, it's critical, 19 informational. They're not so important if they 19 because if a suture breaks because of a loss of 20 don't have an impact on those two endpoints. 20 tensile strength, it can have very serious 21 BY MR. THOMAS: 21 consequences for patients when used for 22 22 Q. And tell the jury what molecular cardiovascular repair. And if there is a loss of strength of 23 2.3 weight is. 24 A. Molecular weight is a measure of the 24 fiber and in mesh, there could be a reduction in 25 length of the polymer chain. The longer the polymer burst strength of the mesh, and so that it doesn't Page 620 Page 622 chain, the heavier its weight. And biomaterials are perform its function as intended. comprised of many chains of polymers. So a higher 2 On Exhibit 2264, which is the 2 Q. 3 molecular weight would suggest a polymer, in this 3 October 15, 1992 report titled, "Seven-Year Data For case, fiber, with a pretty high tensile strength. 4 Ten- Year Prolene Study," ERF-85-219, down under the 5 And what does a change in molecular paragraph headed "IV and GPC," it says: Gel weight tell you as a preclinician? 6 permeation chromatography (GPC) was run on Prolene б 7 7 It gives a measure of the stability sutures explanted from dogs after seven years. The Α. 8 8 of the polymer. GPC data was compared to data from a current 4/0 9 If the molecular weight changes, what 9 Prolene suture. Q. happened to the polymer? 10 What does that mean? 10 11 MR. THORNBURGH: Objection. Outside 11 4/0 suture was the suture size that 12 the scope of his expertise. was implanted in the dogs. And so to make a 13 13 He's already testified at length that relevant comparison, they selected a 4/0 suture out 14 he's not a polymer scientist. I've already asked 14 of package to make the comparisons. him these questions, and he couldn't give me answers 15 Okay. The results indicate there was 15 to them. no significant difference in molecular weight 16 17 17 MR. THOMAS: I don't think you asked between the 4/0 Prolene suture and the seven-year that question. 18 explants. 18 19 What significance of that -- is that 19 But go ahead. 20 MR. THORNBURGH: I did. 20 to you as a preclinician? 21 21 THE WITNESS: Could you repeat, MR. THORNBURGH: Objection. 22 THE WITNESS: That is strong evidence 22 David? 23 BY MR. THOMAS: that there's no polymer degradation taking place. 24 BY MR. THOMAS: 24 What does the change in molecular 25 25 weight tell you as a preclinician? Turn now, please, to Exhibit 2263.

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Page 623 Page 625 1 MR. THORNBURGH: What page is that? I'm sorry. What was the last? 2 MR. THOMAS: The analytical chemistry I'm sorry. 3 3 MR. THOMAS: Exhibit 2263. department notes. The last two numbers are 218. 4 BY MR. THOMAS: 4 MR. THORNBURGH: Got it. 5 5 BY MR. THOMAS: If you go to the last three pages of 6 Exhibit 2263, there is a document titled -- dated 6 And do you understand these to be 7 7 October 19, 1992. notes taken in the analytical chemistry department 8 And it says: Interim report on the 8 for testing conducted on these mesh -- these suture 9 9 physical testing of Prolene, PVDF, Ethilon, and explants? Novofil after seven-year subcutaneous implantation 10 A. 10 Yes. 11 11 in the Beagle dogs. Q. And down to the bottom of the page, 12 Do you see that? 12 it says: Prolene site one and Prolene site six with 13 A. Yes. 13 molecular weights of 322,000 and 323,000 compared to a molecular weight of 324,000. 14 Q. And what is a BSR study? 14 15 BSR is an acronym that stands for 15 What is the significance of that to A. breaking strength retention. 16 16 you as a preclinician? 17 And how does breaking strength 17 MR. THORNBURGH: Objection. Q. 18 THE WITNESS: The polymer is not 18 retention compare to tensile strength? 19 A. Breaking strength retention would be 19 showing any significant changes in molecular weight. 20 determined by tensile testing. 20 And as the comments indicate below, a comparison --21 Basically, they would look at out of 21 and this is a summary of that molecular weight data. 22 package suture and do tensile testing to determine 22 A comparison of seven-year explants 23 breaking strength. And then they would explant 23 to current 4/0 Prolene sutures indicates no suture from these dogs after seven years and do significant degradation. similar tensile testing and make a comparison. BY MR. THOMAS: Page 624 Page 626 And in 1992, tests were conducted, 1 And that's dated October 9, 1992, 2 and it reads here: The attached table shows the 2 down in the lower left by Eugene Muse. 3 physical properties of explanted and baseline 3 A. Yes. October 9, 1992. 4 samples of size 5/0 Ethilon, Novafil, Prolene, and 4 If you turn the page and go to 220. Q. 5 PVDF (N) sutures up to the seven-year mark of the 5 Okay. A. ten-year BSR study. б And 220 is a document dated 6 Q. 7 7 Reading further, it says: Novofil September 21, 1992. The analyst's signature, it 8 samples show a corresponding decrease of 14 percent 8 looks like Robin Ragland, and comparing, again, in breaking strength, while Prolene and PVDF show no 9 Prolene sutures for dog 1995 site three. Do you see significant change after seven years of 10 that? 10 implantation. 11 Yes. 11 A. 12 12 What's the significance of that And the Prolene suture for dog 1995, 13 finding to a preclinician in evaluating the 13 site three, was compared to a current Prolene suture 14 stability of Prolene sutures? 14 4/0.MR. THORNBURGH: Objection. 15 15 Again, what's going on here? THE WITNESS: That's strong evidence 16 Yeah. This is a comparison of the 16 17 molecular weight of the suture from explant compared 17 that there's no degradation of the polymer fiber. 18 BY MR. THOMAS: 18 to a current Prolene suture. 19 19 If you go back to Pages Bates Number And the results indicate, as is 20 09888218, which is going back from the back -- it's 20 stated, that no degradation has taken place. And a few pages in from the back. 21 that's fully supported by the quantitative molecular 21 22 Okay. 22 weight data. Those -- that statement and that data A. 23 Q. Do you have that? 23 is very consistent. 24 24 A. Yeah. And you go to the next page, which is 25 8221, dated August the 5th, 1992, Dan Burkley, 25 MR. THORNBURGH: I am not there yet.

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24 A. Yes. 25 Q. Measure of molecular weight, again, Page 628 1 compared to the control. Do you see that? 2 A. Yes. 3 Q. And what conclusion is reached in 4 1992 about Dog 2008? 5 A. For this dog, they're saying 6 comparison of current Prolene 4/0 suture indicates 7 no significant degradation of seven-year explant. 8 Q. Now, we talked before and went 9 through in great length about the surface cracking 10 that was reserved in the scanning electron 11 microscopy. I don't need to go through that again Page 628 Page 628	2	Page 627		Page 629
Again, they're comparing Prolene the current Prolene control. Is that correct? A. Yes. Q. And they're comparing molecular weights again? A. Yes. Q. And what conclusion do they reach in Cotober in August 1992 about degradation with respect to these suture implants? A. For samples from this dog, they say in the conclusion section: Comparison of seven-year explants to current Prolene indicate no molecular weight degradation. Q. And the next page dated 8222 excuse me numbered 8222, again, is submitted July 2, 1992. A. Okay. Q. I am trying to find my Prolene. Here it is. In the middle? A. Yes. Q. Measure of molecular weight, again, A. Yes. Q. Measure of molecular weight, again compared to the control. Do you see that? A. Yes. Q. And what conclusion is reached in page 628 Comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking through in great length about the surface cracking through in great length about the surface cracking that conclusion to you? MR. THORNBURGH: Objection. BY MR. THOMAS: BY MR. THOMAS: BY MR. THOMAS: BY MR. THOMAS: MR. THORNBURGH: Objection. BY MR. THOMAS: MR. THORNBURGH: Objection. BY MR. THOMAS: MR. THORNBURGH: Objection. BY MR. THOMAS: THE VIDEOGRAPHER: Off the video THE VIDEOGRAPHER: Back on the vid record at 7:00 p.m. MR. THOMAS: THE VIDEOGRAPHER: Back on the vid record at 7:00 p.m. MR. THOMAS: MR. THOMAS: MR. THOMAS: THE VIDEOGRAPHER: Off the video THE VIDEOGRAPHER: Dack on the vid page 628 THE VIDEOGRAPHER: Dack on the vid record at 7:00 p.m. MR. THORNBURGH: THOMAS: MR. THOMAS: MR. THOMAS: MR. THOR	2	signed off by Gene Muse, on October 9, 1992.	1	O. Excuse me. I'm sorry. I have
3 suture explants for Dog 2019, site two and three, to 4 the current Prolene control. Is that correct? 5 A. Yes. 6 Q. And they're comparing molecular 7 weights again? 8 A. Yes. 9 Q. And what conclusion do they reach in 10 October in August 1992 about degradation with 11 respect to these suture implants? 12 A. For samples from this dog, they say 13 in the conclusion section: Comparison of seven-year 14 explants to current Prolene indicate no molecular 15 weight degradation. Q. And the next page dated 8222 16 excuse me numbered 8222, again, is submitted 18 July 2, 1992. 19 A. Okay. 20 Q. I am trying to find my Prolene. 21 Here it is. In the middle? 22 A. Yep. 23 Q. There's Dog 2008, site two? 24 A. Yes. 25 Q. Measure of molecular weight, again, 26 compared to the control. Do you see that? 27 compared to the control. Do you see that? 28 A. Yes. 39 Q. And what conclusion is reached in 40 1992 about Dog 2008? 5 A. For this dog, they're saying 61 comparison of current Prolene 4/0 suture indicates on some of the vide of the control. Do you see that? 4 that conclusion to you? 5 MR. THORNBURGH: Objection. 6 THE WITNESS: I think it demonstrates in in vivo in in vivo system. 9 BY MR. THOMAS: 10 Q. Do any of the documents, the study 11 for the seven-year dog study where there is a discussion of these surface cracks on some of the locations is explanted sutures in some of the locations is there any attribution of cause to that cracking? 15 MR. THOMAS: 16 MR. THOMAS: 17 THE WITNESS: It hink it demonstrates in in vivo in in vivo system. 9 BY MR. THOMAS: 18 MR. THOMAS: 19 Day of the documents, the study 11 for the seven-year dog study where there is a discussion of these surface cracks on some of the explanted sutures in some of the locations is explanted sutures in some of the locations is there any attribution of cause to that cracking? 15 MR. THOMAS: 16 THE WITNESS: It's simply an observation. 18 MR. THOMAS: 18 MR. THOMAS: 19 Day of the documents, the study 10 for the seven-year dog study where th	2		2	
the current Prolene control. Is that correct? A. Yes. Q. And they're comparing molecular weights again? A. Yes. Q. And what conclusion do they reach in October in August 1992 about degradation with respect to these suture implants? A. For samples from this dog, they say in the conclusion section: Comparison of seven-year explants to current Prolene and in the conclusion section. Q. And the next page dated 8222 excuse me numbered 8222, again, is submitted July 2, 1992. A. Okay. Q. I am trying to find my Prolene. Here it is. In the middle? A. Yes. Q. Measure of molecular weight, again. Page 628 THE WITNESS: It his it demonstrates the stability of Prolene suture over seven years in in vivo in in vivo system. Q. Do any of the documents, the study for the seven-year dog study where there is a 2 discussion of these surface cracks on some of the explanted sutures in some of the locations is there any attribution of cause to that cracking? MR. THORNBURGH: Objection. THE WITNESS: It's simply an observation. MR. THOMAS: Can we take a break, please. MR. THOMAS: Can we take a break, please. THE VIDEOGRAPHER: Objection. THE WITNESS: It's simply an observation. MR. THOMAS: Can we take a break, please. THE VIDEOGRAPHER: Objection. THE WITNESS: It's simply an observation. MR. THOMAS: I have no further Page 628	3		3	•
5 A. Yes. 6 Q. And they're comparing molecular 7 weights again? 8 A. Yes. 9 Q. And what conclusion do they reach in 10 October in August 1992 about degradation with 11 respect to these suture implants? 12 A. For samples from this dog, they say 13 in the conclusion section: Comparison of seven-year 14 explants to current Prolene indicate no molecular 15 weight degradation. 16 Q. And the next page dated 8222 17 excuse me numbered 8222, again, is submitted 18 July 2, 1992. 19 A. Okay. 20 Q. I am trying to find my Prolene. 11 Herris is. In the middle? 12 A. Yep. 21 Q. There's Dog 2008, site two? 22 A. Yep. 23 Q. There's Dog 2008, site two? 24 A. Yes. 25 Q. Measure of molecular weight, again. 26 Compared to the control. Do you see that? 27 A. Yes. 38 Q. And what conclusion is reached in 49 1992 about Dog 2008? 40 A. Yes. 41 Compared to the control. Do you see that? 42 A. Yes. 43 Q. And what conclusion is reached in 41 1992 about Dog 2008? 44 Comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. 48 Q. Now, we talked before and went through in great length about the surface cracking the stability of Prolene suture over seven years in in vivo in in vivo system. 8 HP MR. THORNBURGH: Objection. 9 D. Do of these surface cracks on some of the discussion of these surface or the seven-year discussion of these surface or some of the locations is there any attribution of cause to that cracking? 4 MR. THORNBURGH: 5 MR. THORNBURGH: 6 THE WITNESS: I tink it demonstrates the stability of Prolene suture over seven years in in vivo in in vivo system. 9 BY MR. THOMAS: 10 Q. Do any of the documents, the study for the seven-year discussion of these surface cracks on some of the explanted sutures in some of the locations - is there any attribution of cause to that cracking? 11 The WITNESS: It'is kit demonstrates the study for the seven-year blanted discussion of these surface cracks on some of the surface racks on some of the surface and sutures in some of the locat			4	
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A. No thanks. 13 which included the analytical chemistry department	4 5 6 7 8 9 10 11 12	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to.	4 5 6 7 8 9 10 11	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264,
14 Q. But how can you reconcile what was 14 notes.	4 5 6 7 8 9 10 11	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to.	4 5 6 7 8 9 10	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year
15 found as a preclinician, the findings of the 15 MR. THOMAS: 2263, I think.	4 5 6 7 8 9 10 11 12 13	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was	4 5 6 7 8 9 10 11 12 13	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes.
16 scanning electron microscopy with the molecular 16 MR. THORNBURGH: Is it 2263?	4 5 6 7 8 9 10 11 12 13 14 15	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the	4 5 6 7 8 9 10 11 12 13 14 15	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think.
17 weight tensile strength results that are recorded 17 THE WITNESS: Okay.	4 5 6 7 8 9 10 11 12 13 14 15 16	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular	4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263?
18 here? 18 BY MR. THORNBURGH:	4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded	4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay.
19 A. The surface changes are 19 Q. Now, there actually was molecular	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded here?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay. BY MR. THORNBURGH:
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21 scientist, they're not having an adverse impact on 21 explanted Prolene sutures, wasn't there?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded here? A. The surface changes are informational. However, in my mind as a preclinical	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay. BY MR. THORNBURGH: Q. Now, there actually was molecular weight loss in some of the cracked or some of the
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Q. And what importance as a clinician is Q. There was answer my question.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded here? A. The surface changes are informational. However, in my mind as a preclinical scientist, they're not having an adverse impact on molecular weight or tensile strength of the fiber.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay. BY MR. THORNBURGH: Q. Now, there actually was molecular weight loss in some of the cracked or some of the explanted Prolene sutures, wasn't there? A. There was no significant changes.
24 that conclusion to you? 24 Okay? Because I know we both want to get out of	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded here? A. The surface changes are informational. However, in my mind as a preclinical scientist, they're not having an adverse impact on molecular weight or tensile strength of the fiber. Q. And what importance as a clinician is	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay. BY MR. THORNBURGH: Q. Now, there actually was molecular weight loss in some of the cracked or some of the explanted Prolene sutures, wasn't there? A. There was no significant changes. Q. There was answer my question.
25 A. Well 25 here. So answer my question.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. For this dog, they're saying comparison of current Prolene 4/0 suture indicates no significant degradation of seven-year explant. Q. Now, we talked before and went through in great length about the surface cracking that was reserved in the scanning electron microscopy. I don't need to go through that again in any detail unless you want to. A. No thanks. Q. But how can you reconcile what was found as a preclinician, the findings of the scanning electron microscopy with the molecular weight tensile strength results that are recorded here? A. The surface changes are informational. However, in my mind as a preclinical scientist, they're not having an adverse impact on molecular weight or tensile strength of the fiber. Q. And what importance as a clinician is that conclusion to you?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	BY MR. THORNBURGH: Q. Doctor, I appreciate that we've all been here too long today and we're all tired. I do have a couple of questions. I'm going to try to get us all out of here as quickly as I can. Okay? I want to kind of work backwards. I want to turn your attention back to the seven-year dog study, which I think was Exhibit Number 2264, which included the analytical chemistry department notes. MR. THOMAS: 2263, I think. MR. THORNBURGH: Is it 2263? THE WITNESS: Okay. BY MR. THORNBURGH: Q. Now, there actually was molecular weight loss in some of the cracked or some of the explanted Prolene sutures, wasn't there? A. There was no significant changes. Q. There was answer my question. Okay? Because I know we both want to get out of

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	Page 631		Page 633
1		1	
2	There actually was molecular weight loss in some of the explanted Prolene sutures,	2	Q. There was a change in the number as well, wasn't there, Doctor?
3	wasn't there?	3	A. I wouldn't expect these numbers to
4	MR. THOMAS: Object to the form of	4	come out on top of each other.
5	the question.	5	Q. 60,000 in the current Prolene versus
6	THE WITNESS: Let's look at the data.	6	53,000 in the explanted Prolene, correct?
7	I don't recall the specifics.	7	A. That's what it says.
8	BY MR. THORNBURGH:	8	Q. That would indicate there was a
9	Q. Let's turn to ETH.MESH.09888222.	9	reduction in the number of polymer chains, right?
10	A. 232.	10	MR. THOMAS: Object to the form of
11	232.	11	the question.
12	Q. Yes. No. 09888222.	12	THE WITNESS: Well, the conclusion
13	A. 222.	13	says no significant degradation of the seven-year
14	Q. Are you there?	14	explant.
15	A. Yes.	15	BY MR. THORNBURGH:
16	Q. Dog 2008, site two, was compared to	16	Q. Right. The conclusion isn't that
17	current Prolene 4/0 suture, right?	17	there was no degradation; the conclusion is there
18	A. Yes.	18	wasn't significant degradation. But the converse is
19	Q. And the current Prolene suture had a	19	true, that there was evidence of some degradation,
20	molecular weight of 224,000, and an MN of 60,000,	20	wasn't there, Doctor?
21 22	right?	21 22	MR. THOMAS: Object to the form of
23	MR. THOMAS: Object to form. You read that wrong.	23	the question. THE WITNESS: What's important to me
24	THE WITNESS: No. I think it's	24	as a preclinical scientist is what the person doing
25	324,000.	25	the work interprets the results and gives a final
	·		
	Page 632		Page 634
1	BY MR. THORNBURGH:	1	conclusion.
2	Q. 324,000?	2	I know that these molecular weight
3	A. For MW. And 60,000 for MN.	3	numbers can never be identical between samples,
4	Q. Molecular weight was 324,000,	4	because there is a range of molecular weights.
5	correct?	5	BY MR. THORNBURGH:
6	A. Yes.	6	Q. Answer my question, please, Doctor.
7 8	Q. What does MN mean, by the way?	7 8	MR. THOMAS: I think he did. BY MR. THORNBURGH:
9	A. It is a measure of the number of	9	
10	molecular chains versus the average molecular weight of those chains.	10	Q. The finding here was that there was a reduction in molecular weight, and there was a
11	Q. For molecular weight, there was a	11	reduction in the molecular molecules, and that there
12	reduction of the Prolene, current Prolene, compared	12	was some degradation observed of this explant,
13	to the dog explant suture, correct?	13	explanted mesh, correct?
14	MR. THOMAS: Object to the form of	14	MR. THOMAS: Object to the form of
15	the question.	15	the question.
16	THE WITNESS: The number is	16	THE WITNESS: These are two numbers.
17	different, and it's lower.	17	These numbers need to be interpreted.
18	BY MR. THORNBURGH:	18	BY MR. THORNBURGH:
19	Q. It's lower in the explanted Prolene,	19	Q. You can't interpret those numbers?
20	correct?	20	A. They have been interpreted for me as
21	A. Yes, at this site.	21	I read this report.
22	Q. And you said the MN was the number of	22	Q. And there was indication of
23	molecular chains?	23	degradation, wasn't there?
24	A. Yes, in a general way. Again, I'm	24	A. The conclusion say that no
25	not a polymer chemist, but that's my understanding.	25	significant degradation of a seven-year explant.

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Page 635 Page 637 1 1 Q. Which doesn't mean that there wasn't Q. There's three -- three folks that 2 degradation; it just means that there was signed the report, right? 3 degradation but this investigator called it I'm still looking for the summary. I 4 4 insignificant or not significant. Right? can't find it. MR. THOMAS: Object to the form of 5 5 Q. If you look at Exhibit Number 2264. 6 6 MR. THOMAS: Over there in that stack the question. 7 7 THE WITNESS: I would disagree. right there. 8 BY MR. THORNBURGH: 8 THE WITNESS: Okay. 9 9 If we go to -- that's what the BY MR. THORNBURGH: 10 summary is for, too, right, Doctor? Summaries in 10 Okay. And three -- not one Ethicon reports authored by the investigators is to help us 11 employee or Ethicon investigator signed this report, 11 understand their interpretation of the data? 12 but three of them signed the report, right? 12 13 13 A. Absolutely. A. Yes. 14 14 Q. Q. And if we look at the summary of the Which -- and in the report, their 15 conclusions -- which are a summary of the data, 15 conclusions, the three Ethicon employees who right? It's a conclusion of the --16 actually participated in the study, their 16 17 What page are you on? conclusions was that there was degradation in the A. I am looking at Page 2 of -polypropylene, in the Prolene, right? 18 18 19 MR. THOMAS: Dan, just so you know, 19 MR. THOMAS: Object to the form of 20 the full page that talks about molecular weight is 20 the question. 2264. The copy that you have is folded over. I 21 BY MR. THORNBURGH: 21 22 gave you a copy of that already. O. That's their conclusion in the 23 MR. THORNBURGH: I don't know what I 23 report? 24 did with the full page. What is the exhibit number? 24 MR. THOMAS: Object to the form of 25 MR. THOMAS: 2264. the question. Page 636 Page 638 BY MR. THORNBURGH: BY MR. THORNBURGH: 2 If we look at 2264. 2 Q. Q. I'm not -- I am not misreading this 3 A. 2264, yes. 3 right, Doctor? 4 Strike that. Let me just try to see 4 MR. THOMAS: I think you are, Dan. Q. 5 if I can get a clean answer from you, get a clean BY MR. THORNBURGH: б Conclusion. Degradation in Prolene 6 record. 7 7 is still increasing, and PVDF, even though a few You would agree with me that as a 8 scientist, you rely on the conclusions of the 8 cracks were found, is still by far the most surface 9 investigators who conducted the study, right? 9 resistant in-house made suture in terms of cracking. Yes, in large part. 10 I read that correctly, didn't I, 10 A. 11 Q. And the conclusion from the 11 Doctor? MR. THOMAS: Object to the form of 12 investigator who conducted this study was that there 12 13 was --13 the question. 14 A. What page are we on now? 14 THE WITNESS: This is a conclusion 15 Q. If we look at page -- it's Page 2 of 15 for the ophthalmic microscopy and scanning electron 16 the expert report. microscopy section authored by the Elke Lindemann, 17 The ETH.MESH. number? 17 the person who did the SEM evaluation. A. 18 Q. 2264. 18 BY MR. THORNBURGH: 19 MR. THOMAS: Object. Who do you 19 And the conclusion, which was signed 20 attribute to be the investigator? There's three, I 20 off on by three Ethicon employees who -- scientists, 21 21 polymer scientists, right? believe. 22 MR. THORNBURGH: The person who wrote 22 A. Each of the scientists --23 the report. 23 Q. Answer that question first, please. MR. THOMAS: There are three. 24 A. Each of the scientists' names are 24 against the part of the report for which they signed 25 BY MR. THORNBURGH:

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	Page 639		Page 641
1	off.	1	MR. THORNBURGH: What do you mean?
2	Q. Three of them participated in the	2	MR. THOMAS: Just what I said.
3	study, right?	3	THE WITNESS: I am looking at Animal
4	A. That's correct.	4	1995.
5	Q. And the conclusion on Page 2 says:	5	BY MR. THORNBURGH:
6	Degradation in Prolene is still increasing, and	6	Q. So hold on a second. Let's talk
7	PVDF, even though a few cracks were found, is still	7	about Animal 2008, site two.
8	by far the most surface resistant in-house made	8	There was a reduction
9		9	MR. THOMAS: You can do them one at a
10	suture in terms of cracking. Right?	10	
11	MR. THOMAS: Object to the form of	11	time, Tom. You can do them one at a time. If he
12	the question.	12	won't ask you, I'll ask you.
	THE WITNESS: That's one-third of the		THE WITNESS: Fine. Okay.
13	results of this experiment.	13	MR. THORNBURGH: I'll look at all of
14	BY MR. THORNBURGH:	14	them.
15	Q. Well, is that one-third of the	15	THE WITNESS: Fine.
16	results of the experiment in the experiment, they	16	MR. THORNBURGH: I am not afraid of
17	determined that there was degradation, there was	17	the evidence.
18	surface degradation of the Prolene mesh, right?	18	THE WITNESS: Me neither.
19	A. That's what it says.	19	BY MR. THORNBURGH:
20	Q. Or Prolene suture.	20	Q. There is a reduction in the molecular
21	And we can see there was a loss in	21	weight and the number of molecules, right?
22	molecular weight seen on this explant, right?	22	MR. THOMAS: Object to the form of
23	A. Let me get to that section. 222, is	23	the question.
24	that the	24	THE WITNESS: The number is smaller.
25	Q. Yes.	25	The conclusion is that there's no significant
	Page 640		Page 642
1	A. Okay. I'm looking at it.	1	degradation.
2	Q. It doesn't say that there wasn't	2	BY MR. THORNBURGH:
3	degradation, does it?	3	Q. Oh, by the way, did you talk to these
4	A. Well, I let's take a look at all	4	investigators about why there was insufficient
5	the other dogs and see what happened.	5	sample for Prolene IV for this study?
6	Q. Well, I know you don't want to talk	6	A. No, I did not.
7	about the evidence that's not good for Ethicon, but	7	Q. Did you talk to the investigator
8	we got to talk about that evidence, too, Doctor.	8	A. What are we looking at now?
9	MR. THOMAS: Excuse me. Stop, stop.	9	Q. Same page, 222.
10	Just ask a good question. Don't argue with him.	10	A. 222. Insufficient sample for
11	MR. THORNBURGH: It was a good	11	inherent viscosity, not molecular weight.
12	question.	12	Q. Insufficient Prolene sorry.
13	MR. THOMAS: Come on. Stop.	13	Insufficient sample for Prolene IV. Right. That's
14	MR. THORNBURGH: It was a good	14	what that says?
15	question. I'm not making fun of the doctor.	15	A. No. No. It's IV which means
16	MR. THOMAS: Do you want to quit?	16	inherent viscosity.
17	We'll quit.	17	·
	•	18	<u> </u>
18	MR. THORNBURGH: No. That was a good	19	A. It's another measure of polymer characteristics. It's different than a molecular
19	question.		
20	MR. THOMAS: That's ridiculous.	20	weight measurement.
21	MR. THORNBURGH: He didn't want to	21	Q. And that's why it's not included in
22	answer it because because he didn't want he	22	here, right?
\sim	didn't recort the tweth to be beaut		
23	didn't want the truth to be heard.	23	MR. THOMAS: Included where?
23 24 25	didn't want the truth to be heard. MR. THOMAS: I want you to argue that one to the magistrate, to the judge.	24 25	MR. THOMAS: Included where? MR. THORNBURGH: Included right below for the

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Page 643 Page 645 BY MR. THORNBURGH: different, and the Dog 2008 site two is a smaller 1 2 2 I assume -- and you can tell me --3 3 you can answer the question for me, if you can. MR. THORNBURGH: Is that the section 4 The IV results --4 that you wanted me to go back to and ask questions 5 MR. THOMAS: They're above, Dan. 5 6 MR. THORNBURGH: Hold on one second. 6 MR. THOMAS: You can ask whatever you 7 7 BY MR. THORNBURGH: want to. I'm not going to tell you what to do. 8 Q. Is this the IV results here? 8 BY MR. THORNBURGH: 9 9 A. IV/DLG, that is an IV result. If you go to 8221. 10 Q. Okay. I'm sorry. 10 A. 8221. Okay. They're saying they could not --11 There was insufficient sample of 11 A. Q. 12 there was insufficient sample to determine an IV 12 Prolene for IV again, right? measurement for Prolene suture. 13 13 A. That's correct. 14 14 Q. And what is an IV measurement? Q. Then, also, again, insufficient 15 It represents inherent viscosity, 15 sample of Prolene IV again here, right? You see it A. again, a measure -- it's a polymer characteristic. 16 says insufficient Prolene IV. And then it also says 16 17 Would it give us information about insufficient Prolene IV here. And it doesn't give the loss of the polymer? 18 18 numbers for the Prolene. 19 A. I don't know for certain. I think 19 MR. THOMAS: It does at the bottom. 20 it's a different endpoint, but I don't know for 20 Current molecular weight right there on the bottom. 21 21 certain. MR. THORNBURGH: We're going to talk 22 22 Q. In any case, they're able to test all about that -- we're going to talk about that in a of the other samples except for Prolene for that 2.3 moment. 23 study, right, for IV? 24 MR. THOMAS: I thought you were 25 That's what it says, yes. 25 A. suggesting --Page 644 Page 646 1 Q. If you go to 8221. 1 BY MR. THORNBURGH: 2 MR. THOMAS: Do you want to ask the 2 Because right here, they separate it 3 rest of the questions about the molecular weight out, right? In both cases, it says insufficient down at the bottom of that page? 4 sample for Prolene IV. MR. THORNBURGH: I see Prolene wasn't 5 5 That is just written twice. A. included in that -- in this section of molecular б Do you know why there would be б Q. 7 7 weight. Right? insufficient samples for Prolene IV? 8 MR. THOMAS: Oh, I think it is. 8 No, I do not. I know you need to 9 THE WITNESS: No. That's IV. have a certain mass in order to do the experiment. And the analytical work was done on the strand 10 Molecular weight is above to the right. 10 BY MR. THORNBURGH: breaks after Instron testing. So maybe there was 11 11 just not enough mass to run the experiment, a 12 Q. Okay. I'm sorry. 13 A. So --13 certain sample requirement. 14 Q. What's this -- what's this data right 14 And for molecular weight, current 15 here? 15 Prolene, there's -- the explants in this sample were also lower than the -- than the control, correct? 16 That's -- that's molecular weight 16 MR. THOMAS: Object to the form of data for the other suture -- sutures. 17 17 the question. That's not true. 18 Okay. And the molecular weight data 18 here we've already discussed, which showed a 19 THE WITNESS: No, that's not correct. 19 20 reduction in the molecular weight from the current 20 BY MR. THORNBURGH: Prolene to the explant and, also, a reduction in the 21 334,000 -number of molecules, correct? 22 22 MR. THOMAS: No. 23 MR. THOMAS: Object to the form of 23 BY MR. THORNBURGH: 24 24 the question. -- is greater than 331,000. THE WITNESS: The numbers are 25 25 MR. THOMAS: You're not reading the

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	Page 647		Page 649
1		1	
1 2	number right, Dan. It's 324,000. MR. THORNBURGH: Oh, okay. I'm	1 2	the significance of that in polymer science, but I can't shed much light on it.
3	apparently dyslexic today.	3	Q. You didn't talk to anybody, right?
4	BY MR. THORNBURGH:	4	A. That's correct.
5	Q. So there was in this in this	5	Q. You didn't call up Dan Burkley or the
6	sample, there wasn't degradation observed, molecular	6	other two investigators and say, hey, why is
7	degradation, right?	7	there why weren't you able to do Prolene IV
8	A. Well, to use your language from the	8	studies?
9	previous dog, there were increases in molecular	9	A. That's correct.
10	weight for two strands.	10	Q. So the people most knowledgeable
11	Q. There wasn't molecular weight	11	about that that particular issue in this study
12	degradation; there wasn't a decrease in the	12	wouldn't include you; it would include somebody
13	molecular weight seen in this sample. Right?	13	else?
14	A. There was an increase.	14	A. At this level of detail, yes.
15	Q. There wasn't a reduction in there	15	Q. It would appear, though, that IV had
16	wasn't look at the conclusion.	16	analysis is related in some way to a degradation
17	The conclusion was no molecular	17	analysis, right?
18	weight degradation, right?	18	MR. THOMAS: Object to the form of
19	A. That's right.	19	the question.
20	MR. THOMAS: That's fine.	20	THE WITNESS: No, I don't think so.
21	THE WITNESS: That's right.	21	MR. THORNBURGH: We'll mark as
22	BY MR. THORNBURGH:	22	Exhibit 2265.
23	Q. Molecular weight degradation. That's	23	(Document marked for identification
24	what they call it here, right?	24	as Exhibit T-2265.)
25	A. That's right. What this is	25	BY MR. THORNBURGH:
	Page 648		Page 650
1	suggesting is that molecular weight rises and falls	1	Q. A degradation analysis of Prolene
2	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator	2	Q. A degradation analysis of Prolene explants.
2	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator needs to make a judgment whether or not the movement	2	Q. A degradation analysis of Prolene explants. MR. THOMAS: Where did this come
2 3 4	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator needs to make a judgment whether or not the movement from the baseline is sufficient to call out	2 3 4	Q. A degradation analysis of Prolene explants. MR. THOMAS: Where did this come from?
2 3 4 5	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator needs to make a judgment whether or not the movement from the baseline is sufficient to call out significant degradation. That's how science works.	2 3 4 5	Q. A degradation analysis of Prolene explants. MR. THOMAS: Where did this come from? MR. THORNBURGH: This is
2 3 4 5 6	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator needs to make a judgment whether or not the movement from the baseline is sufficient to call out significant degradation. That's how science works. Q. Again, there's insufficient sample	2 3 4 5 6	Q. A degradation analysis of Prolene explants. MR. THOMAS: Where did this come from? MR. THORNBURGH: This is MR. THOMAS: A lab notebook?
2 3 4 5 6 7	suggesting is that molecular weight rises and falls in comparison to a control, and the investigator needs to make a judgment whether or not the movement from the baseline is sufficient to call out significant degradation. That's how science works. Q. Again, there's insufficient sample for Prolene IVs, right?	2 3 4 5 6 7	Q. A degradation analysis of Prolene explants. MR. THOMAS: Where did this come from? MR. THORNBURGH: This is MR. THOMAS: A lab notebook? MR. THORNBURGH: I believe so, yes.
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1	A. No. I can't explain that in any	1	attorneys Ethicon has been in possession of this
2	detail.	2	since 1987 did not provide this information to
3	Q. Nobody at Ethicon provided you with	3 4	you, correct? A. I have not seen this information.
4 5	this study that showed that in 1987, the explants showed that there the conclusions from studies of	5	
6	explants was that it was degraded Prolene?	6	Q. So you're not prepared to talk about that study or any other studies from the notebooks?
7	MR. THOMAS: Object to the form of	7	MR. THOMAS: We've already said that
8	the question. He's not prepared to talk on this.	8	a hundred times.
9	We've been through this at length.	9	MR. THORNBURGH: We'll have to come
10	BY MR. THORNBURGH:	10	back.
11	Q. My question is: Nobody at Ethicon,	11	MR. THOMAS: I understand.
12	nor Ethicon's counsel, provided you with this study	12	BY MR. THORNBURGH:
13	that showed the explanted Prolene was degraded?	13	Q. Now, you represented that there were
14	MR. THOMAS: Object to the form of	14	20 binders in front of you and behind you which
15	the question.	15	included studies that you that Ethicon
16	BY MR. THORNBURGH:	16	Ethicon's attorneys and you compiled together for
17	Q. Right?	17	purposes of this deposition, right?
18	A. I've not seen this. I am not	18	A. Yes.
19	really I'm not prepared to talk about it. It is	19	Q. And you you have to agree that
20	a bit of information in isolation. I don't	20	many of the studies that were copied and put in
21	understand the context. I'd have to look at all	21	these binders are actually duplicates of studies in
22	at all the data around it.	22	other binders in front of you, right?
23	Q. Nobody nobody showed you this	23	A. That's correct.
24	conclusion either, or this study either, prior to	24	Q. Many of them, a vast majority of
25	coming here today, a study that they've had	25	them?
	Page 652		Page 654
1	apparently in Ethicon's files since 1987, which	1	A. That's correct.
2	showed that the explanted meshes the explant	2	Q. It's not actually 20 binders of
3	mesh	3	different studies. There's 20 binders where the
4	MR. THOMAS: Are you referring to	4	majority of those are duplicate copies, right?
5	something new? Or is this the same document?	5	A. I never represented them as
6	MR. THORNBURGH: Same document.	6	individual lists of studies that were not
7	THE WITNESS: It's a notebook page.	7	duplicates.
8	BY MR. THORNBURGH:	8	Q. I just want to make sure the jury
9	Q. Nobody showed you this document	9	understands. It's not actually 20 binders of
10	either?	10	studies, of different studies. There's 20 binders
11 12	A. It's a notebook page. Q. Nobody showed you the study results	11 12	with lots of duplication, right?
13	Q. Nobody showed you the study results from Professor Godoin? Professor Godoin. Nobody	13	A. Yes. There's overlap between the topics of discussion.
14	showed you Professor Godoin's explants and the	14	Q. In fact, some studies are contained
15	studies that were done on Professor Godoin's	15	within are duplicated 10 and 11 times in these
16	explants which showed evidence of polypropylene	16	binders, right?
17	degradation?	17	A. I don't think there were that many
18	MR. THOMAS: Object to the form of	18	topics for discussion.
19	the question.	19	Q. Or duplicated in each one of the
20	THE WITNESS: If there's anything in	20	topics?
21	any notebooks that you want to talk about, I'm not	21	A. Okay.
22	prepared to talk about it.	22	Q. Right? Correct?
23	BY MR. THORNBURGH:	23	A. That could be so.
24	Q. Yeah. So nobody showed you this	24	Q. Exhibit 2262, the list of studies.
25	study, right? Nobody at Ethicon, nor Ethicon's	25	A. Okay.

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Page 655 Page 657 Now, we've marked that as an exhibit. 1 study. 1 Q. 2 Do you have it in front of you? 2 Okay. And then you have degradation 3 3 here, which could include surface degradation, A. Yes. Okay. You have a list of studies 4 Q. 4 correct? 5 and -- that you included or somebody included in the 5 If it were significant enough to be Α. 6 degradation section of Exhibit 2262, correct? 6 seen at the light microscope level in an H&E 7 7 Yes. A. section, yes. 8 8 Q. And can you tell me in exhibit -- or Q. What do you mean by absorption? 9 in Study Number 1, study of tissue reaction of 9 For absorbable implants, there's an colorless and pigmented monofilament polypropylene 10 absorption of the material into the surrounding 10 sutures, was there SEM, SEM EDX, GPC, DTP, or FTIR tissues. That's not the case for a non-absorbable, 11 11 studies conducted? 12 which is Prolene. 12 13 13 A. No. Q. And what do you mean by "edge 14 Q. 14 erosion"? And to determine if there was 15 actually actual degradation of the polypropylene in 15 There might be degradation of the these cases, a number of studies would have to be 16 surface which would be reflected by inflammatory 16 conducted, right? A number of tests? 17 cells scalloping the perimeter of the implant, Not necessarily. One can determine 18 18 fiber. 19 quite a bit by looking at the tissue reaction from 19 Q. Now, for these studies that you 20 an implanted material and whether or not there's any 20 listed here in degradation, the overwhelming evidence that there's cracking, degradation, majority of these studies weren't studies that 21 21 absorption, edge -- edge erosion. 22 looked at FTIR analysis, scanning electron 22 SEM -- SEM --23 O. 23 microscopy, scanning electron microscopy EDX, GPC, 24 MR. THOMAS: Excuse me. or those other tests, degradation tests, correct? 25 BY MR. THORNBURGH: 25 MR. THOMAS: Object to the form of Page 656 Page 658 I'm sorry. I thought you were done. the question. 2 I didn't mean to interrupt you. 2 THE WITNESS: Yes. It's all right. I'm done. 3 A. 3 BY MR. THORNBURGH: 4 Q. I see the period. Now -- or I hear 4 In fact, can you point to any of 5 the period. 5 these studies that you have listed in the б degradation section of your -- your notebooks that б Doctor, are you telling the ladies 7 7 and gentlemen of the jury that SEM analysis alone is did FTIR microscopy? 8 sufficient to determine degradation or surface Seven-year dog study. Α. 9 degradation of a polymer fiber? 9 Q. That's it? That's the only one that Absolutely not. you can point to, right? 10 A. 10 11 Q. Additional testing could be 11 A. Yes. 12 12 conducted, right? And the seven-year dog study through 13 Yeah, as was done in the seven-year 13 FTIR found degradation, correct? A. MR. THOMAS: No. Object to the form 14 dog study. 14 15 15 of the question. Q. You said that -- you testified a moment ago that one can determine the tissue BY MR. THORNBURGH: 16 16 reaction from implanted material and whether or not 17 There were carbonyl bands that were 17 18 there's any evidence that there's cracking, 18 consistent with oxidation, correct? degradation, absorption, edge erosion. 19 MR. THOMAS: Object to the form of 19 20 So I am going to break that down for 20 the question. BY MR. THORNBURGH: 21 a moment. Okay? 21 22 A. Okay. 22 Correct? Q. 23 O. So one can determine through light 23 A. I recall some language about a 24 microscopy or SEM surface cracks, correct? 24 possibility of such a thing, but nothing definitive. 25 25 As was done in the seven-year dog There were carbonyl bands that were

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1	Page 659		Page 661
_	seen that were consistent with oxidation, according	1	of listen. I am summarizing.
2	to the report.	2	The only study listen, Dave. I
3	MR. THOMAS: Object to the form of	3	would appreciate if you would stop coaching this
4	the question.	4	witness.
5	THE WITNESS: No, they we can go	5	MR. THOMAS: I am not coaching the
6	to the report and look.	6	witness.
7	BY MR. THORNBURGH:	7	MR. THORNBURGH: You are. You have
8	Q. Okay.	8	been coaching him for the last two days, Dave. I
9	MR. THOMAS: It's on Page 1, I	9	don't do that to you.
10	believe.	10	MR. THOMAS: Stop, please.
11	THE WITNESS: There would be an	11	MR. THORNBURGH: I have respect for
12	ETH.MESH.09888187, whereas I have recalled the	12	you. I treat you like a professional.
13	statement says, showed possible evidence of slight	13	MR. THOMAS: I bet you do.
14	oxidation.	14	MR. THOMAS. 1 bet you do. MR. THORNBURGH: You don't treat me
15	BY MR. THORNBURGH:	15	like a professional. You don't act professional
16		16	when I am asking questions. You coach the witness.
17		17	BY MR. THORNBURGH:
18	your 40 some studies that actually did FTIR microscopy found that the IR spectra obtained for	18	
19	* · · · · · · · · · · · · · · · · · · ·	19	Q. The only study that you listed in
	cracked Prolene specimens showed possible evidence		your degradation section of the studies that were
20	of slight oxidation, correct?	20	compiled by you or someone for Ethicon or Ethicon's
21	A. I think I just said that.	21	attorneys say show showed evidence of
22	Q. Correct?	22	possible evidence of oxidation and degradation,
23	A. Yes.	23	right?
24	Q. The only study that you listed in	24	A. We've discussed this line several
25	your degradation study or degradation list of	25	times today.
	Page 660		Page 662
1	studies that actually did FTIR microscopy showed	1	Q. And the answer is yes, correct?
2	evidence of degradation.	2	A. It showed possible evidence of slight
3	MR. THOMAS: Object to the form of	3	degradation. What's written is undeniable.
	41		
4	the question.	4	THE WITNESS: I am hoping to wrap
4 5	BY MR. THORNBURGH:	4 5	THE WITNESS: I am hoping to wrap this up soon, Dave. I am running out of steam.
	*		
5	BY MR. THORNBURGH: Q. Right?	5	this up soon, Dave. I am running out of steam.
5 6	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of	5 6	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand.
5 6 7	BY MR. THORNBURGH: Q. Right?	5 6 7	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished?
5 6 7 8	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH:	5 6 7 8	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I
5 6 7 8 9 10	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir?	5 6 7 8 9	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here.
5 6 7 8 9 10 11	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate?	5 6 7 8 9 10 11	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got
5 6 7 8 9 10 11 12	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in	5 6 7 8 9 10 11 12	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting
5 6 7 8 9 10 11 12	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way.	5 6 7 8 9 10 11	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying
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5 6 7 8 9 10 11 12 13 14 15 16	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262	5 6 7 8 9 10 11 12 13 14 15 16	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm
5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262 that actually looked at FTIR microscopy found	5 6 7 8 9 10 11 12 13 14 15 16 17	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm tired, too.
5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262 that actually looked at FTIR microscopy found evidence of oxidation and degradation, correct?	5 6 7 8 9 10 11 12 13 14 15 16 17 18	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm tired, too. THE WITNESS: and if it's going to
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262 that actually looked at FTIR microscopy found evidence of oxidation and degradation, correct? MR. THOMAS: Object to the form of the question. Read it correctly, please.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm tired, too. THE WITNESS: and if it's going to go beyond five minutes, we need to schedule more time.
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262 that actually looked at FTIR microscopy found evidence of oxidation and degradation, correct? MR. THOMAS: Object to the form of the question. Read it correctly, please. MR. THORNBURGH: Read it correctly? I wasn't reading anything. MR. THOMAS: Read what the report	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm tired, too. THE WITNESS: and if it's going to go beyond five minutes, we need to schedule more time. MR. THORNBURGH: I'm tired, too, Doctor. MR. THOMAS: Let's go. Let's go.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. THORNBURGH: Q. Right? MR. THOMAS: Object to the form of the question. BY MR. THORNBURGH: Q. Right, sir? A. Can you restate? Q. Yeah. Yeah. And I can try to ask in a better way. The only study that you can identify right now for the ladies and gentlemen of the jury in your list of degradation studies on Exhibit 2262 that actually looked at FTIR microscopy found evidence of oxidation and degradation, correct? MR. THOMAS: Object to the form of the question. Read it correctly, please. MR. THORNBURGH: Read it correctly? I wasn't reading anything.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	this up soon, Dave. I am running out of steam. MR. THOMAS: I understand. Just in light of what he said, are you getting close to being finished? MR. THORNBURGH: Yeah. I got I only have a few little notes here. MR. THOMAS: Well, last time that got a little bit too late, and the witness is getting tired. I'm just trying THE WITNESS: I'm getting tired. And if you've got a lot of questions to ask MR. THORNBURGH: I'm tired, too. I'm tired, too. THE WITNESS: and if it's going to go beyond five minutes, we need to schedule more time. MR. THORNBURGH: I'm tired, too, Doctor.

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			Page 665
-		1	
1	today, aren't you?	1	INSTRUCTIONS TO WITNESS
2	A. Like I said, you've got five minutes.	2	701 1 1 1
3	I am running out of energy. If you need more time,	3	Please read your deposition over
4	we'll have to reschedule more time.	4	carefully and make any necessary corrections. You
5	Q. How much money are you getting paid	5	should state the reason in the appropriate space on
6	by the hour by Ethicon to come in here and testify	6	the errata sheet for any corrections that are made.
7	as a 30(b)6 witness?	7	After doing so, please sign the
8	A. You know that it's \$225 an hour.	8	errata sheet and date it. It will be attached to
9	You've asked me before. And that's the same reason	9	your deposition.
10	I gave	10	It is imperative that you return the
11	MR. THOMAS: Whoa, whoa, whoa. Just	11	original errata sheet to the deposing attorney
12	relax. Just don't you're asking questions over	12	within thirty (30) days of receipt of the deposition
13	and over again. Let's ask the questions and move	13	transcript by you. If you fail to do so, the
14	on.	14	deposition transcript may be deemed to be accurate
15	MR. THORNBURGH: I hear you. I know	15	and may be used in court.
16	you're tired. I am going to pass the witness.	16	
17	MR. THOMAS: Thank you. That's all	17	
18	we have. Thanks very much.	18	
19	THE VIDEOGRAPHER: It's now 7:33, and	19	
20	we're concluded with Tape Number 6 in the videotape	20	
21	deposition of Thomas A Barbolt.	21	
22	(Witness excused.)	22	
23	(Deposition concluded at	23	
24	approximately 7:33 p.m.)	24	
25	approximately , tee printy	25	
	Page 664		Page 666
١.			
1	OF DIVING A TIP	1	
2	CERTIFICATE		ERRATA
4		3	PAGE LINE CHANGE
5	I HEREBY CERTIFY that the witness was	4	PAGE LINE CHANGE
6	duly sworn by me and that the deposition is a true	5	REASON
7	record of the testimony given by the witness.	6	REASON
8	given by the winness.	7	REASON
9	It was requested before completion of	8	
10	the deposition that the witness, THOMAS A. BARBOLT,	9	REASON
11	Ph.D., have the opportunity to read and sign the	10	REASON
12	deposition transcript.	11	REASON
13		12	
14		13	REASON
15		14	
16		15	REASON
17	MICHELLE L. GRAY, a Registered	16	READOIN
	Professional Reporter, Certified	17	REASON
18	Shorthand Reporter and Notary Public	18	READOIN
1.0	Dated: January 16, 2014	19	REASON
19 20		20	
21	(The foregoing certification of this	21	REASON
22	transcript does not apply to any reproduction of the	22	
23	same by any means, unless under the direct control	23	REASON
24	and/or supervision of the certifying reporter.)	24	
	and of supervision of the certaining reporter.)		
25		25	REASON

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	Page 667
1 2 3 4 5 6 7 8 9 10 11 12 13	ACKNOWLEDGMENT OF DEPONENT I,
14 15 16 17	THOMAS A. BARBOLT, Ph.D. DATE Subscribed and sworn to before me this day of, 20 My commission expires:
21 22 23 24 25	Notary Public
1 2 3 4 5 6 7 8 9 10 11 12	Page 668 LAWYER'S NOTES PAGE LINE
13 14 15 16 17 18 19 20 21 22 23 24 25	

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